

# **I. OVERVIEW OF THE FUNDING OPPORTUNITY**

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Amyotrophic Lateral Sclerosis Research Program**

**Therapeutic Development Award**

**Announcement Type: Modified**

**Funding Opportunity Number: HT942524ALSRPTDA**

**Assistance Listing Number: 12.420 Military Medical  
Research and Development**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Letter of Intent Submission Deadline:** 5:00 p.m. Eastern time (ET), June 18, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, July 10, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, July, 17, 2024
- **Peer Review:** September 2024
- **Programmatic Review:** November 2024

*This program announcement must be read in conjunction with the General Application Instructions, version 900. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Amyotrophic Lateral Sclerosis Research Program (ALSRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the ALSRP in 2007 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the ALSRP from FY07 through FY23 totaled \$229.4 million (M). The FY24 appropriation is \$40.0M.

### II.B. Award Information

The FY24 ALSRP Therapeutic Development Award supports research ranging from preclinical validation of therapeutic leads through Food and Drug Administration (FDA) Investigational New Drug (IND)-enabling studies. The proposed studies are expected to be empirical in nature and product-driven. Applicants with limited ALS experience are strongly encouraged to include collaborators with substantial experience in the relevant ALS model systems, endpoints, and pathophysiology.

**Applications supported by this award must begin with lead compounds in hand and must already demonstrate proof-of-concept efficacy data in at least one preclinical model system of ALS, including whole animal and cellular model systems.**

Examples of activities that will be supported by this award include:

- 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.
- Validation of pilot efficacy studies (such as from an ALSRP Therapeutic Idea Award [TIA]), including the use of additional ALS model systems and/or replicating preliminary data with more time points or additional doses.
- 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.

Applicants seeking support for basic research focused on ALS drug discovery are encouraged to apply for the FY24 ALSRP TIA (Funding Opportunity Number HT942524 ALSRP TIA), which does not require preliminary data (<https://cdmrp.health.mil/funding/alsrp>).

**Mechanism-specific, predictive/cohort-selective, target engagement, and pharmacodynamic biomarker development, in parallel to the main therapeutic effort, is a critical component of the FY24 ALSRP Therapeutic Development Award.** If 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 apparent in the application. Development of biomarkers for the purposes of diagnosis, prognosis, or measurement of general disease progression without consideration of the therapeutic development process will not be supported. Applicants seeking support for biomarker development independent of therapeutic development are encouraged to apply for the FY24 ALSRP Clinical Outcomes and Biomarkers Award (Funding Opportunity Number HT942524ALSRPCOBA).

For further information on biomarker types, qualifications, and use in ALS clinical trials, it is recommended that applicants consult the following resources:

- FDA/National Institutes of Health (NIH) Biomarkers, EndpointS, and Other Tools (BEST) Resource (<https://www.ncbi.nlm.nih.gov/books/NBK338448/>)
- FDA Guidance Document – “Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry.” September 2019. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/amyotrophic-lateral-sclerosis-developing-drugs-treatment-guidance-industry>
- Verber NS, Shephard SR, Sassani M, et al. 2019. Biomarkers in motor neuron disease: A state of the art review. *Frontiers in Neurology* 10:291. <https://www.frontiersin.org/articles/10.3389/fneur.2019.00291/full>
- van den Berg LH, Sorenson E, Gronseth G, et al. 2019. Revised Airlie House consensus guidelines for design and implementation of ALS clinical trials. *Neurology* 92(14):e1610-e1623. <https://n.neurology.org/content/92/14/e1610>
- Benatar M, Boylan K, Jeromin A, et al. 2016. ALS biomarkers for therapy development: State of the field and future directions. *Muscle Nerve* 53(2):169-182. <https://doi.org/10.1002/mus.24979>

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

***Clinical trials are not allowed under this award mechanism.*** However, validation of treatment approaches in appropriately powered and controlled studies using biological correlates of disease activity and progression in preexisting, de-identified human specimens from well-characterized patient cohorts is permitted and is encouraged. Examples of acceptable sources for preexisting biosamples or datasets include controlled clinical trials, observational studies, publicly available biorepositories, and registries. A list of suitable resources can be found on the ALSRP web page, <https://cdmrp.health.mil/alsrp/resources/ALSRPresources>. Other resources may be used, provided they have an adequate description of repository parameters and mechanisms for broad

access. Active-duty military and/or Veteran patient populations or resources should be considered. ***All clinical specimens must exist at the time of application submission; collection of new specimens will not be supported.***

***A clinical trial is defined*** in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

***Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.***

***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** ***Clinical research*** encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
- (2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.
- (3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#).

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 ALSRP Therapeutic Development Award should not exceed **\$1.5M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

***The CDMRP expects to allot approximately \$9.6M to fund approximately four Therapeutic Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this***

*funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

**Extramural Organization:** An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

**Intramural DOD Organization:** Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible **organizations**, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

### **II.C.1.b. Principal Investigator**

Independent investigators at all career levels may be named by their organization as the PI on the application.

For titles outside of academia that may not be analogous to traditional hierarchies, investigators at or above an independent scientist level may be named by their organization as the PI on the application.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## II.D. Application and Submission Information

### II.D.1. Location of Application Package

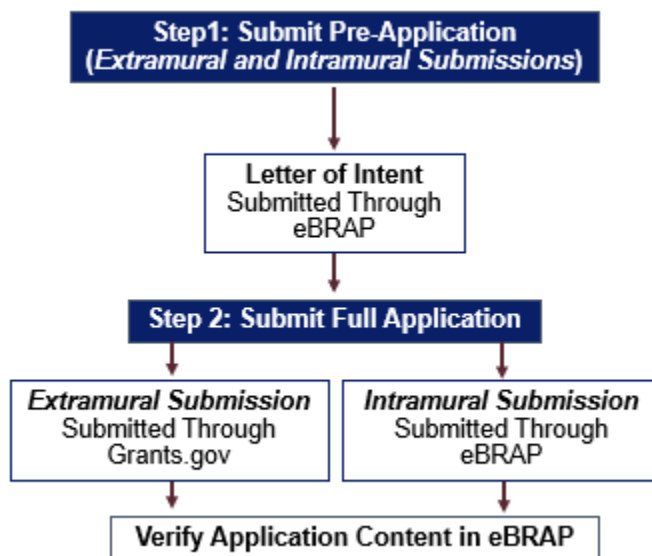
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

**eBRAP** (<https://ebrap.org>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

**Grants.gov** (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

#### *Application Submission Workflow*



**Extramural Submission:** An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for

HT942524ALSRPTDA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ALSRPTDA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

## **II.D.2. Content and Form of the Application Submission**

***Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).***

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at <https://cdmrp.health.mil/funding/researchDup>.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 ALSRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

### **II.D.2.a. Step 1: Pre-Application Submission**

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.



If any changes need to be made, the applicant should contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

#### **II.D.2.a.i Pre-Application Components**

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the therapeutic to be studied and the development steps to be achieved in this research project.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

#### **II.D.2.b. Step 2: Full Application Submission**

##### **II.D.2.b.i. Full Application Submission Type**

**Extramural Submissions:** Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

**Intramural Submissions:** Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

##### **II.D.2.b.ii. Full Application Submission Components**

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

**(a) SF424 Research & Related Application for Federal Assistance Form (*Extramural Submissions Only*):** Refer to the General Application Instructions, Section IV.B, for detailed information.

**(b) Attachments:**

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (12-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Rationale for Candidate Therapeutic:** Provide background information supporting validation and further development of a proposed lead compound(s) and its putative mechanism of action as a viable therapeutic approach. Explain how the proposed study is empirical in nature and product driven.
  - Provide the chemical (or biological) identities of the lead molecules(s) or limited group of specific lead compounds.
  - Provide proof of identity and purity of the lead(s) (for small molecules, typically >95% by nuclear magnetic resonance, liquid chromatography–mass spectrometry [LC-MS], melting point, etc., with no single impurity >0.5%. For biologics, often by high-performance liquid chromatography, LC-MS, immunochemistry, nucleotide or amino acid sequence analysis, etc.). Describe other physical, chemical, and/or biological properties of the lead(s) as appropriate.
  - Provide clear efficacy data in at least one relevant preclinical ALS model, with adequate power and methods.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy and Specific Aims:** Concisely explain the project’s specific aims to be funded by this award. Provide a well-developed, well-integrated research plan that explains how the research plan will meet the research goals and milestones. Describe the study design, methods, models, and analyses (including appropriate controls) in sufficient detail for assessment of feasibility. Explain how the study design and methods support rational design, translatability, and promise of the approach. Describe how each study is designed to achieve reproducible and rigorous results, including controls.
  - Describe how the existing or proposed biomarker(s) will demonstrate target engagement, help refine individual patient or patient subgroup selection, and

clarify the biological impact of a potential therapeutic. Describe how qualification criteria described in relevant ALS biomarker literature is being addressed. Additional details of the biomarker effort(s) should be provided in [Attachment 6, Biomarker Statement](#).

- For efficacy studies involving preclinical ALS models, describe the rationale for the choice of model(s), and the dose(s) of the drug.
  - Describe the chemical synthetic pathways associated with proposed lead compound(s) and the feasibility of modification and/or formulation of potential delivery systems.
  - Provide data to support use of primary and secondary in vitro bioactivity studies for optimization or structure–activity relationships.
  - Provide data to support target selectivity, engagement, and desirable activity at the intended target.
  - Describe the statistical plan, including power analysis, for the research proposed.
  - Address potential pitfalls and problem areas and present alternative methods and approaches.
- **Clinical Impact:** State explicitly how the proposed work will have significant clinical impact including the target population. Outline, in general terms, steps to transition the study outcomes to therapeutic application. *Additional details describing impact should be provided in [Attachment 7, Impact Statement](#).*
  - **Transition Readiness:** Explain how the proposed approach will prepare the candidate therapeutic for the transition to clinical studies. Outline to steps required to achieve regulatory submissions (e.g., IND). *Additional details describing a transition plan should be provided in [Attachment 8, Transition Plan](#).*
  - **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

*There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.*

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). *Do not duplicate the Data and Research Resources Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing

located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP’s expectations for making data and research resources publicly available.

- **Use of DOD/U.S. Department of Veterans Affairs (VA) Resources (if applicable):** Provide a signed letter of support confirming access for the entire period of performance to active-duty military population, VA patients, and/or VA/DOD resources, databases, or research space. Provide any details on arrangements or agreements required to access and publish data here.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Background:** Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Describe the study design, including appropriate controls.
- **Product:** Describe the therapeutic product to be developed and the validated biomarker(s) or biomarker development/characterization proposed.
- **Impact:** Summarize briefly how the proposed project will impact ALS therapeutic development and the ALS community.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. *Do not duplicate the technical abstract.*

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine.* Avoid overuse of scientific jargon, acronyms, and abbreviations.

- Summarize the objectives and rationale for the proposed research.
- What are the potential applications, benefits, and risks of the anticipated outcomes?

- What type of ALS patients will it help, how will it help them, and when will this likely happen?
- What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the FY24 ALSRP Therapeutic Development Award, refer to the “Example: Assembling a Generic Statement of Work”, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application.

- **Attachment 6: Biomarker Statement (no page limit): Required for all applications. Upload as “Biomarker.pdf”.** Development of mechanism-specific (1) predictive/cohort-selective, (2) target engagement, and (3) pharmacodynamic biomarkers should be incorporated into the application. 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. Preliminary biomarker characterization must address qualification criteria described in relevant ALS biomarker literature. [See Section II.B, Award Information](#), for more information on relevant ALS biomarker literature.

Provide the following information:

- **Biomarker(s) Description:** Describe the biomarker(s) and the theoretical or empirical basis for its potential utility. Biomarkers may reference levels of analytes in fluids or samples, radiologically measured parameters, event time frames, or any other objectively measured values used to reach a single interpretation. Specify the aspect of the biomarker that is measured and the form in which it is used for biological interpretation.
- **Purpose in ALS Drug Development:** Describe how the proposed biomarkers will demonstrate target engagement, help refine individual patient or patient subgroup selection, and/or clarify biological impact of a potential therapeutic. Describe the extent to which the biomarker results will be used to steer the development process. Describe how the preliminary biomarker characterization addresses qualification criteria described in relevant ALS biomarker literature. *The inclusion of a decision-tree diagram that explicitly illustrates the application of the biomarkers and includes the actions that would be taken based on the biomarker results is*

***recommended.*** Describe how easily and reliably the biomarkers may be implemented in eventual clinical trials of the proposed novel therapeutic. **Include a description of regulatory considerations for use in future ALS clinical trials.**

- **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”.**  
Describe how the proposed work will impact development of therapeutics for ALS. Articulate a pathway to making a clinical impact for individuals with, or at risk for, ALS. This should be written in a manner readily understood by readers without background in science or medicine, at or around the eighth-grade level. Specifically highlight how the research will achieve the following by the end of the performance of period:
  - Advance the development of a groundbreaking ALS therapeutic.
  - Further validate biomarkers in parallel with the main therapeutic effort for use in eventual clinical trials.
  - Prime the therapeutic and/or biomarkers for rapid clinical impact in the intended patient populations (including subpopulations).
  - Lead to meaningful improvements in patient care.
- **Attachment 8: Transition Plan (three-page limit): Upload as “Transition.pdf”.**  
Describe/discuss the methods and strategies proposed to move the product to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Outline the regulatory strategy. The post-award transition plan should include the components listed below.
  - The development and/or commercialization strategy.
  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the FDA regulatory strategy, to include considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice guidelines, if appropriate.
  - Details of the funding strategy to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
  - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A “knowledge product” is a non-materiel product that addresses an identified need, topic area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior



throughout the continuum of care, including primary prevention of negative outcomes.

- A schedule and milestones for transitioning the technology or knowledge product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA). Include identification of the FDA regulatory strategy (if appropriate).
- A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 9: Animal Research Plan (three-page limit), if applicable: Upload as “AnimalPlan.pdf”.** When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:
  - Describe consideration of the guidelines for working with ALS animal models.
  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) were chosen to address the scientific objectives and, where appropriate, the study’s relevance to human biology.
  - For efficacy studies, provide the rationale for the dose and route of administration for the drug(s).
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Attachment 10: Representations (Extramural Submissions Only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/>)



[public/Program.htm](https://ebrap.org/eBRAP/public/Program.htm)). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form (if applicable):** Upload as “IGBudget.pdf”. If an [intramural DOD organization](https://ebrap.org/eBRAP/public/Program.htm) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) **Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
  - **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”.
  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
  - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch\_LastName.pdf”.
    - Include biographical sketches for collaborators, if applicable
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
  - **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

**(f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

**(g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

#### **II.D.2.c. Applicant Verification of Full Application Submission in eBRAP**

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the [application verification period](#). The full application cannot be modified once the application verification period ends.

#### **II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)**

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

#### **II.D.4. Submission Dates and Times**

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

## **II.D.5. Funding Restrictions**

The maximum period of performance is **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **\$1.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 ALSRP Therapeutic Development Award.

## **II.D.6. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Rationale for Candidate Therapeutic**
  - How strongly the project background supports the applicant's reasoning that the proposed therapeutic approach is feasible for validation and further development and the extent to which the study is product driven.
  - Whether further preclinical development of an identified bioactive compound or group of lead compounds is supported by clear efficacy in at least one ALS-relevant model system, with adequate power and methods.

- **Research Strategy and Feasibility**

- How well the experimental design, methods, and analyses, including statistical analyses, support the study outcomes.
- To what extent the theoretical arguments and/or empirical data support use of the proposed biomarkers for target engagement, biological effect, and/or to predict whether the therapeutic will be effective in individual patients or patient subgroups.
- How well the preliminary biomarker characterization addresses qualification criteria described in relevant ALS biomarker literature. How well regulatory considerations for use in future ALS clinical trials are described.
- How well the applicant identifies potential pitfalls and problem areas and addresses alternative methods and approaches.

***For manufacturing/chemistry manufacturing and controls/IND-enabling studies:***

- How appropriate and well-developed the primary and secondary in vitro bioactivity assays are for optimization or structure–activity relationship studies.
- How appropriate and well-developed the described target engagement and selectivity assays are for measurement of desirable activity at the intended target, for assessing artifacts, and for assessing the potential for undesirable activities at related but unintended targets.
- How feasible modification and/or formulation of potential delivery systems are for the outlined chemical synthetic pathways associated with the lead compound(s).

***For studies involving animal research:***

- How well the animal species, strain, and model(s) being used can address the scientific objectives.
- For efficacy studies, whether the drug dose(s) and route(s) of administration are justified.
- How well each animal study considers the guidelines for working with ALS animal models and how well it is designed to achieve the objectives, including the relevance of endpoints/outcome measures to be used.
- The extent to which each study is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- **Transition Readiness**

- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- Whether the schedule and milestones for bringing the product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.
  - Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.
  - How the regulatory strategy and the development plan to support the planned product label, if applicable, are appropriate and well-described.
  - Whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.
  - How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.
  - The extent to which the use of the proposed biomarkers(s) will enhance future clinical trials, and the feasibility of their implementation in clinical settings.
- **Clinical Impact**
    - To what extent does the proposed research advance the development of a novel ALS therapeutic.
    - To what extent the research further validates biomarkers in parallel with the main therapeutic effort for use in eventual clinical trials.
    - To what extent the therapeutic and/or biomarkers will be ready for clinical implementation in the intended patient populations (including subpopulations/subtype of ALS) at the conclusion of the proposed project.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Personnel**
  - How appropriate the levels of effort are for successful conduct of the proposed work.
  - How appropriate the research team members' backgrounds and expertise are for development of the proposed product and conduct of the proposed research.

- **Budget**
  - Whether the budget is appropriate for the proposed research.
  - Whether the direct costs exceed the allowable direct costs as published in the program announcement.
- **Environment**
  - To what extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 ALSRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact, including transition potential, and/or military benefit

#### **II.E.2. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not*

*automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the ALSRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization.*** No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

***Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.***

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

***If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

## **II.F.2. PI Changes and Award Transfers**

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

## **II.F.3. Administrative and National Policy Requirements**

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.



Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D Terms and Conditions](#) and the [USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions](#) for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local IACUC, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

#### **II.F.4. Reporting**

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

**Award Expiration Transition Plan:** An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

#### **II.G. Federal Awarding Agency Contacts**

##### **II.G.1. eBRAP Help Desk**

*Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission*

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

## **II.G.2. Grants.gov Contact Center**

*Questions regarding Grants.gov registration and Workspace*

Phone: 800-518-4726; International 1-606-545-5035

Email: [support@grants.gov](mailto:support@grants.gov)

## **II.H. Other Information**

### **II.H.1. Program Announcement and General Application Instructions Versions**

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

### **II.H.2. Administrative Actions**

After receipt of full applications, the following administrative actions may occur.

#### **II.H.2.a. Rejection**

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

#### **II.H.2.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

#### **II.H.2.c. Withdrawal**

The following may result in administrative withdrawal of the full application:

- An FY24 ALSRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 ALSRP Programmatic Panel members can be found at <https://cdmrp.health.mil/alsrp/panels/panels24>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.

#### **II.H.2.d. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

#### **II.H.2.e. Other Funding Opportunities**

The ALSRP is committed to leveraging efforts with other funding organizations to accelerate progress in ALS research. At the time of funding notifications, the ALSRP may inform highly rated, unfunded applicants about opportunities to provide their ALSRP applications and peer review summary statements to non-governmental funders, who will determine the specific criteria for funding consideration.

### II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
<b>SF424 Research &amp; Related Application for Federal Assistance</b> (Extramural submissions only)	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> (Intramural submissions only)	<input type="checkbox"/>
<b>Attachments</b>	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Biomarker Statement – Attachment 6, upload as “Biomarker.pdf”	<input type="checkbox"/>
Impact Statement – Attachment 7, upload as “Impact.pdf”	<input type="checkbox"/>
Transition Plan – Attachment 8, upload as “Transition.pdf”	<input type="checkbox"/>
Animal Research Plan – Attachment 9, upload as “AnimalPlan.pdf”	<input type="checkbox"/>
Representations (Extramural submissions only) – Attachment 10, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 11, upload as “IGBudget.pdf”	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
<b>Research &amp; Related Budget</b> (Extramural submissions only) Include budget justification	<input type="checkbox"/>
<b>Budget</b> (Intramural submissions only) Include budget justification	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> (if applicable)	<input type="checkbox"/>
<b>Additional Application Components</b>	<input type="checkbox"/>
<b>Confidential Letters of Recommendation</b>	<input type="checkbox"/>

## **APPENDIX 1: ACRONYM LIST**

ACURO	Animal Care and Use Review Office
ADME	Absorption, Distribution, Metabolism, and Excretion
ALS	Amyotrophic Lateral Sclerosis
ALSRP	Amyotrophic Lateral Sclerosis Research Program
BEST	Biomarkers, EndpointS, and Other Tools
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COBD	Clinical Outcomes and Biomarkers Award
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
LC-MS	Liquid Chromatography–Mass Spectrometry
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TDA	Therapeutic Development Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs