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 Idea Award

Announcement Type: Initial

Funding Opportunity Number: HT942524ALSRPTIA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 24, 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 901. 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 Idea Award (TIA) supports new, innovative, high-risk, high-gain ideas aimed at Amyotrophic Lateral Sclerosis (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. **Projects that focus primarily on pathophysiology of ALS without development of a therapy are outside the scope of this funding opportunity**.

Applications may demonstrate the ability to achieve interpretable results in the absence of preliminary data supporting the hypothesis. While the inclusion of preliminary data is not prohibited, ***the strength of the application should rely on the approach***.

The key elements of this award mechanism are:

- **Innovation:** Research deemed innovative may introduce a new paradigm, challenge current paradigms, introduce novel concepts or technologies, or exhibit other uniquely creative qualities that may lead to potential therapeutics for ALS.

- **Impact:** The FY24 TIA can be for a specific ALS subtype and does not have to broadly apply to all patients. Research **should be non-incremental** and pioneer transformative results that could lay the foundation for a new direction in the field of ALS therapy development. Incremental research does not meet the intent of this funding opportunity.

- **Strong Scientific Rationale**: Projects that address in the intent of the mechanism should include a well-formulated, testable hypothesis based on strong scientific rationale that holds translational potential to improve ALS treatment and/or advance a novel treatment modality.

- **Biomarkers**: Applicants are required to include consideration to biomarker(s) development in parallel with their proposed Therapeutic Idea Award research for eventual clinical trials. Efforts should be mechanism-specific and may include development of target engagement biomarkers, objective pharmacodynamic biomarkers to measure the biological effect of an

investigational therapeutic, or predictive/cohort-selective biomarkers that indicate whether a specific therapy will be effective in an individual patient or patient subgroup, including pre-symptomatic gene carriers. Development of markers for the purposes of diagnosis, prognosis, or measurement of disease progression apart from consideration of the therapeutic development process will not be supported and instead investigators should consider the Clinical Outcomes and Biomarkers Award (HT942524ALSRPCOBA).

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

o BEST (Biomarkers, EndpointS, and other Tools) Resource.
https://www.ncbi.nlm.nih.gov/books/NBK326791/

o National Institute of Neurological Disorders and Stroke (NINDS) Biomarker Program.
https://www.ninds.nih.gov/current-research/focus-tools-topics/focus-biomarkers-research

o U.S. Food and Drug Administration (FDA) Biomarker Qualification Program.
https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/biomarker-qualification-program

o 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

o Verber NS, Shepheard 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

o 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

o 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

– **Expected outcomes**: Projects should strive to produce the type and amount of data needed to apply for the next stage of therapy development, i.e., ALSRP Therapeutic Development Award or other mechanisms for ALS therapeutic advancement.

Additional Considerations:

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.

Standards for Preclinical Study Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (https://www.nature.com/articles/nature11556). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 8, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

Guidelines for the Use of ALS Animal Models: Many factors must be considered in the design of studies using animal models of ALS. A number of investigators and organizations have published guidelines and recommendations for the design of ALS animal model studies. Applicants are strongly encouraged to become familiar with the concepts presented in the articles listed below and to incorporate recommendations contained therein in their study designs. While most of the recommendations pertain to the SOD1-G93A transgenic mouse model, many general concepts for using animal models for ALS research are also described, including the following:

- Ludolph AC, Bendotti C, Blaugrund E, et al. 2010. Guidelines for preclinical animal research in ALS/MND: A consensus meeting. *Amyotrophic Lateral Sclerosis* 11(1-2):38-45. https://dx.doi.org/10.3109/17482960903545334

- Scott S, Kranz JE, Cole J, et al. 2008. Design, power, and interpretation of studies in the standard murine model of ALS. *Amyotrophic Lateral Sclerosis* 9(1):4-15. https://dx.doi.org/10.1080/17482960701856300

- Ludolph AC, Bendotti C, Blaugrund E, et al. 2007. Guidelines for the preclinical *in vivo* evaluation of pharmacological active drugs for ALS/MND: Report on the 142nd ENMC International Workshop. *Amyotrophic Lateral Sclerosis* 8(4):217-223. https://dx.doi.org/10.1080/17482960701292837

This award may not be utilized to conduct part or all of a clinical trial.

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 Idea Award should not exceed **$600,000.**

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 $9.8M to fund approximately 10 Therapeutic Idea 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 any career stage may be supported as Principal Investigator.

An eligible Principal Investigator (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
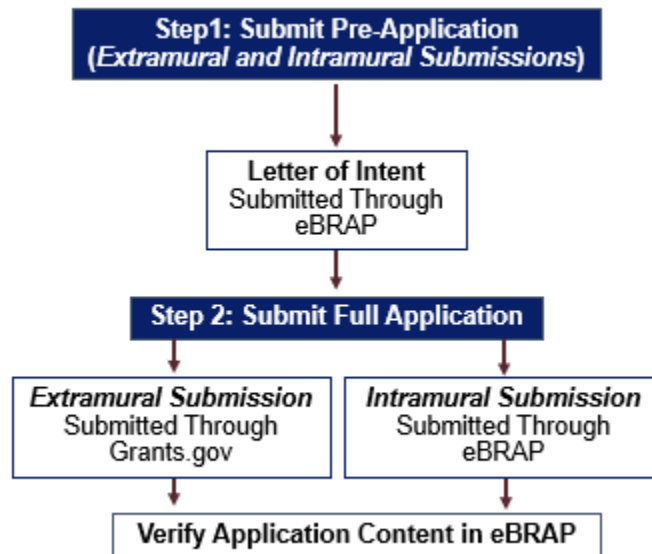
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524ALSRPTIA 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 HT942524-ALSRPTIA 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 or 301-682-5507.

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

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

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 or 301-682-5507 prior to the application submission deadline.

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 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 research to be conducted.

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.

– The Project Narrative should be structured in accordance with the outline below. If necessary, additional subheadings may be used.

– **Innovation:** Describe how the project may introduce a new paradigm, challenge current paradigms, introduce novel concepts or agents, or exhibit other uniquely creative qualities that may lead to potential therapeutics for ALS. For hypothesis-generating research that may be high-risk, clearly describe the potential gain and anticipated advancements in ALS therapeutic development.

– **Scientific Rationale:** Present the scientific rationale behind the proposed work. Explain how the novel idea is supported by sound logical reasoning and strong scientific rationale. Cite relevant, published literature and, if applicable, any preliminary data (preliminary data are not required). Applicants from outside the ALS research field are encouraged to include collaborators with the necessary relevant expertise, such as experience with ALS model systems, endpoints, and pathogenic findings.

– **Hypothesis or Objective:** State the hypothesis(es) to be tested or the objective(s) to be reached.

– **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how the proposed tools or models are suited to, and will be used for, preclinical testing or development of therapeutics, as opposed to basic pathophysiology research. If applicable, how well the animal study considers the guidelines for working with ALS animal models and is designed to achieve the objectives, including the relevance of the model and endpoints/outcome measures to be used. Address potential problem areas and present alternative methods and approaches. As the Therapeutic Idea Award is designed to be a "high-risk/high-reward" mechanism, hypotheses may prove incorrect, but the proposed experiments must be feasible and designed to adequately test the hypotheses.

– **Next Steps:** Describe the next steps to transition the study outcomes into further therapeutic application(s) including how the project will produce the type and amount of data needed to apply for the next stage, i.e., ALSRP Therapeutic Development Award or other mechanisms to advance ALS therapeutic advancement.

– **Biomarker:** Clearly state the biomarker category and describe how the proposed marker will demonstrate target engagement, help refine individual patient or patient subgroup selection, and/or clarify biological impact of a potential ALS therapeutic. Describe potential regulatory considerations for use in ALS clinical trials. *Additional details of the marker effort should be provided in [Attachment 9, Biomarker Statement](#).*

○ **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 (2-page limit per letter *is recommended*):** 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)* (2-page limit per letter *is recommended*):** 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.

- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."

  - **Intellectual and Material Property Plan** *(if applicable)***:** Provide a plan for resolving intellectual and material property issues among participating organizations.

  - **Commercialization Strategy** *(if applicable)***:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **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.

- **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.

- **Innovation:** Summarize briefly the innovative aspects of the proposed project.

- **Impact:** Summarize briefly how the proposed project will impact the development of therapeutics for ALS.

○ **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 use of scientific jargon, acronyms, and abbreviations.

- Describe the ultimate applicability of the research.

- What type of ALS patients will it help, and how will it help them?

- What are the potential clinical applications, benefits, and risks?

- What is the projected time it may take to achieve a patient-related outcome? If the research is too basic for clinical applicability, describe the interim outcomes.

- What are the likely contributions of this study in advancing the development of therapeutics for ALS?

○ **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 Idea Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

○ **Attachment 6: 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. Specifically highlight how the research will achieve the following by the end of the performance period:

- Advance the development of a groundbreaking ALS therapeutic, including for specific subset populations.

- Show potential for application in the clinic and ultimate impact on ALS patient populations.

- Advance biomarkers with the potential for meaningful treatment outcomes in parallel with the main therapeutic development effort (if applicable).

○ **Attachment 7: Data and Research Resources Sharing Plan (one-page limit): Upload as "Sharing.pdf".** Describe how data and resources generated during the performance of the project will be shared with the research community. Describe whether the proposed plan for data sharing includes existing, publicly available, curated ALS repositories/data platforms or other resources with relevant repository parameters and mechanisms for broad access to data and samples and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner. A list of suitable resources can be found on the ALSRP web page (https://cdmrp.health.mil/alsrp/resources/ALSRPresources). Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. Include plans for making raw data available in appropriate publicly accessible ALS databases at the time of publication or at the time of conclusion of the funding. The government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations. Note that this document may be used in programmatic review deliberations.

○ **Attachment 8: 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:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

- 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).

○ **Attachment 9: Biomarker Statement (five page limit): Upload as "Biomarker.pdf".** 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 marker(s) and the theoretical or empirical basis for its potential utility. Markers 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 marker that is measured and the form in which it is used for biological interpretation.

- **Purpose in ALS Drug Development:** Describe how the proposed marker(s) 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 marker results will be used to steer the development process. Explain how the 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 marker(s) and includes the actions that would be taken based on the marker results is recommended.*** Describe how easily and reliably the biomarker may be implemented in eventual clinical trials of the proposed novel therapeutic, including regulatory considerations.

  ○ **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). 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](#) 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".

  - – For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

  - – For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information

(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.

- o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- o **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 **2** years

The Therapeutic Idea Award application's direct costs budgeted for the entire period of performance should not exceed **$600,000**. 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 **2** years.

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 **2** years.

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- 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 Idea 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 listed in decreasing order of importance**:

- **Innovation**

   o How well the research introduces a new paradigm, challenges current paradigms, introduces novel concepts or agents, or exhibits other uniquely creative qualities that may lead to potential therapeutics for ALS.

   o If the project includes potentially high-risk research, how well the potential gain and anticipated advancements in ALS therapeutic development are described. Innovative uses or investigations of previously developed resources are acceptable.

- **Impact**

   o To what extent the research will make a significant contribution toward the development of groundbreaking therapeutics for ALS, including for specific subset populations.

   o How well the next steps for further therapeutic development are articulated, including how the project will produce the type and amount of data needed to apply for the next stage of funding.

- How well the potential impact of the therapeutic on ALS patient populations is described. The project may focus on one specific subtype of ALS and does not need to apply to all types of ALS.

- **Research Strategy and Feasibility**

  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and/or by logical reasoning.

  - Whether the proposed experiments and analysis are well integrated and likely to generate conclusive answers to the proposed hypotheses, whether positive or negative. As the Therapeutic Idea Award is designed to be a "high-risk/high-reward" mechanism, hypotheses may prove incorrect, but the proposed experiments must be designed to adequately test the hypotheses.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.

  - How well the potential challenges and alternative strategies are identified.

  - If applicable, whether the ALS model group size is described and the method by which it was derived, including power analysis calculations.

  - If applicable, whether the proposed ALS animal model(s), endpoints/measures, and data analyses, including statistical methods, are appropriate and whether the study design incorporates existing ALS model use guidelines.

- **Biomarker Statement:**

  - How well the preliminary biomarker characterization considers qualification criteria described in relevant ALS biomarker literature.

  - How well theoretical arguments and/or empirical data support the utility of the proposed biomarker to demonstrate target engagement, help refine individual patient or patient subgroup selection, and/or clarify biological impact of a potential therapeutic.

  - How well the application describes the extent to which the biomarker results will be used to steer the development process.

  - How easily and reliably the biomarker(s) could be implemented in eventual clinical trials of the proposed novel therapeutic.

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**:

- **Data Sharing**

- How well data and resources generated during the performance of the project will be shared with the research community.

- The extent that the proposed plan for data sharing includes existing, publicly available, curated ALS repositories/data platforms or other resources with relevant repository parameters and mechanisms for broad access to data and samples.

- How well the plan describes whether organizational and technical capabilities are sufficient to share project data in a timely manner.

- **Personnel**

  ○ How appropriate the levels of effort are for successful conduct of the proposed work.

  ○ The extent to which the background, expertise, and levels of effort of the PI and key personnel will contribute to the success of the proposed project.

  ○ If early-career investigators or applicants from outside the ALS research field are named as PI, whether collaborators with the necessary relevant expertise, such as experience with ALS model systems, endpoints, and pathogenic findings, are included as part of the research team.

- **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 DHP and FY24 ALSRP, as evidenced by the following:

    ○ Adherence to the intent of the funding opportunity \

    ○ Program portfolio composition

    ○ Relative impact and innovation and/or military benefit

    ○ Appropriateness of the Data and Research Resources Sharing Plan

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, 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.

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

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

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

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 pre-applications or full applications, the following administrative actions may occur.

II.H.2.a. Rejection

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

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

The following will result in administrative rejection of the pre-application:

- Pre-application was not submitted.

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ALS	Amyotrophic Lateral Sclerosis
ALSRP	Amyotrophic Lateral Sclerosis Research Program
ARRIVE	Animal Research: Reporting In Vivo Experiments
BEST	Biomarkers, EndpointS, and Other Tools
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COBA	Clinical Outcomes and Biomarkers Award
DHP	Defense Health Program
DOD	Department of Defense
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TIA	Therapeutic Idea 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