Program Announcement for the Defense Health Agency

Amyotrophic Lateral Sclerosis Research Program

Therapeutic Development Award

Funding Opportunity Number: HT942526ALSRPTDA

Pre-Application Due: June 24, 2026

Application Due: September 30, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Amyotrophic Lateral Sclerosis Research Program (ALSRP) Therapeutic Development Award (TDA) supports research ranging from preclinical validation of therapeutic leads through U.S. 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 amyotrophic lateral sclerosis (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 appropriate preclinical model system of ALS, including whole-animal and cellular model systems.

Distinctive Features: ***Mechanism-specific, predictive/cohort-selective, target engagement and pharmacodynamic biomarker development, in parallel to the main therapeutic effort, is a critical component of the FY26 ALSRP Therapeutic Development Award***. If appropriate 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 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.

Therapeutic candidates which have already been granted an IND are not appropriate for this mechanism.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $12.0 million (M) to fund approximately six Therapeutic Development Award applications with total cost caps of $2.0M per award. The maximum period of performance is three years. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 24, 2026
- **Invitation to Submit an Application:** August 3, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, September 30, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, October 6, 2026
- **Peer Review:** November 2026
- **Programmatic Review:** January 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526ALSRPTDA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

2.1.2. Principal Investigator

Independent investigators affiliated with an eligible organization are eligible to be named Principal Investigator (PI) on the application, regardless of ethnicity, nationality or citizenship status. An investigator may be named as PI on no more than three FY26 ALSRP applications across all award mechanisms, in any combination.

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.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Amyotrophic Lateral Sclerosis Research Program (ALSRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. 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 FY25 totaled $309.4M. The FY26 appropriation is $40.0M.

The Vision of the FY26 ALSRP is to improve outcomes and find cures for people with ALS. The Mission is to fund and accelerate research that translates science into effective ALS treatments. The program will prioritize applications that support the vision and mission of the FY26 ALSRP.

3.1. Award History

The ALSRP Therapeutic Development Award mechanism was first offered in FY07. Since then, 313 Therapeutic Development Award applications were received, and 49 were recommended for funding.

3.2. Intent of the Therapeutic Development Award

The FY26 ALSRP Therapeutic Development Award supports research ranging from preclinical validation of therapeutic leads through FDA 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. Candidate therapeutics that already have been granted an IND are not appropriate for the TDA.

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 appropriate preclinical model system of ALS, including whole-animal and cellular model systems.

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

- Lead optimization, including confirmation of candidate therapeutics obtained from screening or by other means, such as optimization of potency and pharmacological properties and testing of derivatives and sister compounds.
- Validation of preliminary efficacy findings, building on initial discoveries from pilot studies through expansion on assessed ALS model systems, extended dose-response characterization or extended timepoints to more robustly establish therapeutic potential.
- IND-enabling studies to include: compound characterization; absorption, distribution, metabolism, and excretion studies; studies on formulation and stability leading to Good Manufacturing Practice (GMP) production methods; and dose/response and toxicology studies in relevant model systems.
- 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.

Applications supported by this award must begin with lead compounds in hand and must include preliminary data relevant to the phase of development, such as:

- Proof of identity and purity.
- Selectivity for the intended target over closely related targets.
- Availability of primary and secondary in vitro bioactivity assays for optimization or structure–activity relationship studies.
- Availability of clear efficacy data in at least one appropriate preclinical ALS model, with adequate power and methods.

3.2.1. Key Elements for the TDA

Mechanism-specific, predictive/cohort-selective, target engagement, and pharmacodynamic biomarker development, in parallel to the main therapeutic effort, is a critical component of the FY26 ALSRP Therapeutic Development Award (TDA).

If appropriate 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 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 FY26 ALSRP Clinical Outcomes and Biomarkers Award (Funding Opportunity Number HT942526ALSRPCOBA).

Applicants are encouraged to consult the following resources for additional information regarding biomarker Context of Use (COU) in ALS clinical trials:

- FDA-NIH Biomarker Working Group, *BEST (Biomarkers, EndpointS, and other Tools) Resource* (U.S. Food and Drug Administration, 2016+), https://www.ncbi.nlm.nih.gov/books/NBK326791/.
- FDA Center for Drug Evaluation and Research, *Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry* (FDA, 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/amyotrophic-lateral-sclerosis-developing-drugs-treatment-guidance-industry.
- Leonard H van den Berg et al, "Revised Airlie House Consensus Guidelines for Design and Implementation of ALS Clinical Trials," *Neurology* 92, no. 14 (2019): e1610-e1623, https://pubmed.ncbi.nlm.nih.gov/30850440/.
- Nick S. Verber et al, "Biomarkers in Motor Neuron Disease: A State of the Art Review," *Frontiers in Neurology* 10 (2019): 291, https://www.frontiersin.org/articles/10.3389/fneur.2019.00291/full.
- Michael Benatar et al, "ALS Biomarkers for Therapy Development: State of the Field and Future Directions," *Muscle Nerve* 53, no. 2 (2016): 169-182, https://doi.org/10.1002/mus.24979.

For further information on new drug applications, biologics license applications, or applications for supplemental indications on the evidence to be provided to demonstrate effectiveness, it is recommended that applicants consult the following resource:

- FDA Center for Biologics Evaluation and Research, *Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products* (FDA, 2019),

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/demonstrating-substantial-evidence-effectiveness-human-drug-and-biological-products.

For biomarker development efforts proposing to use large datasets for training predictive models, a discussion of mechanisms for addressing rigor in model design, training, and assessment should be provided. Depending upon the context, this might include: algorithmic designs to avoid overfitting, saliency analysis, feature attribution, node ablation, or other alternate strategies.

3.2.2. Other Important Considerations for the TDA

The ALSRP aims to improve the health, care, and well-being of military Service Members, Veterans, their Families and the American public affected by ALS. Evidence from scientific research suggests a relationship between ALS and military service, with a higher rate of incidence in the Veteran population, without any known reason(s) for this incidence. Knowledge, information, products, or technologies gained from the proposed research should advance research that is of significance to Service Members, Veterans and/or their Families.

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

Clinical trials are not allowed within this funding opportunity. 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. 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.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

3.3. Funding Instrument

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

3.4. Funding Details

Period of Performance: The maximum period of performance is **three** years.

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$2.0M**. 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 **three** years.

The appropriateness of the budget for the proposed research will be assessed during peer review.

Direct Cost Restrictions: 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. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the ALSRP Therapeutic Development Award.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Pre-Application Components

Pre-application submissions must include the following components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit 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 that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Rationale for Candidate Therapeutic:** Concisely state the project's objectives to support development of a candidate therapeutic. Describe the lead compound(s) already in hand and include preliminary data relevant to the phase of development, including relevant physical, chemical, and/or biological properties and efficacy in at least one relevant ALS model with adequate power and methods.
  - **Clinical Impact:** State explicitly how the proposed work will have significant clinical impact on the target population, including specific ALS subtypes. Outline, in general terms, steps to transition the study outcomes to therapeutic application.
  - **Research Strategy (including a biomarker-driven approach):** Describe the project's specific aims supporting development of a candidate therapeutic. **Mechanism-specific** predictive/cohort-selective, target engagement, and pharmacodynamic biomarker development, in parallel to the main therapeutic effort, is a critical component of the research strategy. If mechanism-specific biomarkers are already available or currently in development, how the existing biomarkers will improve trial study design, patient selection, and efficiency or interpretation of the proposed ALS therapeutic approach must be described. **The existence or inclusion of mechanism-specific biomarker development in the Research Strategy is a requirement for all Therapeutic Development Award applications**, including research strategies focused on translational efficacy or on Chemistry, Manufacturing and Controls processes.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
    - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
    - **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
    - **Key Personnel Biographical Sketches: *All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

4.3. Full Application Components

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

IMPORTANT: *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".**

  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.
        - Confirm whether the lead compound(s) is already in hand. 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 analysis data and brief description of 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 statistical analysis of 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.
  - Briefly introduce the existing or proposed biomarker(s) and its Contexts of Use. ***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 methods and power analysis, for the proposed research.
  - Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Address potential pitfalls and problem areas and present alternative methods and approaches.
  - Applications involving artificial intelligence should include details regarding the specific platforms and approaches that will be implemented.
- **Clinical Impact:** Briefly state how the proposed work will have significant clinical impact and advance the development of a novel ALS therapeutic. Describe the target population. Briefly 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:** Specify the current stage of the candidate therapeutic within the FDA IND-enabling pathway, or international equivalent. Explain how the proposed approach will prepare the candidate therapeutic for the transition to clinical studies. ***Additional details describing a transition plan should be provided in Attachment 8, Transition Plan.***
- **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory

expert, patient advocate). ***Inclusion of a biomarker interpretation expert is highly encouraged.***

- If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, Appendix 4, for additional considerations.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

  There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).
  - **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; include 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 the original or present government award under which the facilities or equipment items are now accountable. A standardized form for this information does not exist.
  - **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 Support (two-page limit per letter is recommended):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
  - **Sex as a Biological Variable Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or

other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the ALS research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived, if applicable. ***Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations).*** The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

  Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan which will be requested only after a recommendation for funding is made.

  Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

  Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project. Clearly define the goals of the effort/study.
  - **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.
  - **Relevance to Military Health:** Briefly describe how the proposed research is relevant to Service Members, Veterans and their Families.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid

overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

- Summarize the goals, objectives and rationale for the proposed research.
- What population will the research help, and how will it help them?
- What are the potential applications, benefits and risks of the anticipated outcomes?
- What are the likely contributions of the proposed research project to advancing research, patient care and/or quality of life?
- What type of ALS patients will it help, how will it help them, and when will this likely happen?
- How is the proposed research relevant to Service Members, Veterans and their Families?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to Example: Assembling a Generic Statement of Work. Include milestones for data or research resource(s) sharing.

- **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 3.2.1, Key Elements for the TDA, 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, 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 the mechanism-specific 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 section should be written in a manner readily understood by readers without a background in science or medicine.** Overly technical jargon should be avoided and technical terms, if any, should be defined.

  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 biomarker for rapid clinical implementation in the intended patient populations (including subpopulations).
  - Lead to meaningful improvements in patient care.
  - Describe how knowledge, information, products, or technologies gained from the proposed research advance research that is of significance to Service Members, Veterans and/or their Families.
  - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

  Key points may be presented as bullet points to emphasize the main study goals. Inclusion of a simple diagram of the proposed study, if plausible, is encouraged.

- **Attachment 8: Transition Plan (three-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to feasibly move the project's findings 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, including steps required to achieve regulatory submissions (e.g., IND). **The ALSRP evaluates TDA success based on whether the candidate therapeutic is ready for IND/IDE submission or further optimization upon completion of the award.** A Regulatory Compliance Specialist or Technology Transfer Expert may be recruited to peer review the application.

  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.
  - A description of the scientific or technical requirements needed to advance the research findings, such as manufacturing readiness, analytical validation, assay reproducibility, device classification analysis, etc.
  - An assessment of the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the study results into clinical practice.

- A timeline with defined milestones and deliverables describing the expected post-award progress of the results toward the next phase of development and eventual clinical impact. This may include a sequenced development pathway, defined regulatory inflection points and realistic time-to-execution assumptions.
- Details of the funding strategy that will be used to bring the outcomes to the next phase of development. Provide sufficient evidence that the PI has, or can secure, additional funding, and describe potential options to secure the additional funding needed to bring the outcomes to the next phase of development (e.g., specific potential industry partners; specific funding opportunities to apply for).
- A description of collaborations, infrastructure, and other resources that will be leveraged to provide continuity of development or clinical implementation.
- A plan to distribute the findings or intervention to the ALS community.
- A risk analysis for cost, schedule, manufacturability and sustainability.

○ **Attachment 9: Animal Research Plan (three-page limit), if applicable: Upload as "AnimalPlan.pdf".** ***Attachment 9 is only applicable and required for applications proposing animal studies.*** If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. 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 Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results 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) being used can 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 *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**
- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526ALSRPTDA from Grants.gov or eBRAP, depending on which submission portal will be used.

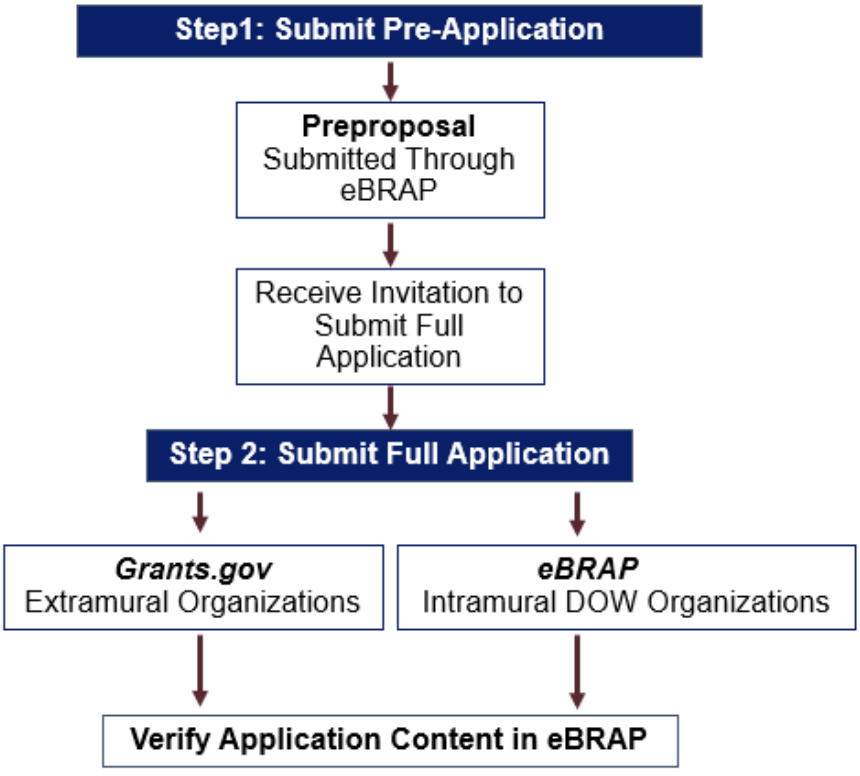
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

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. Contact the eBRAP Help Desk if any changes need to be made.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

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.

Members of the FY26 ALSRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 ALSRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the Defense Health Program and the ALSRP, pre-applications will be screened based on the following criteria:

- **Rationale for Candidate Therapeutic:** How well the project's objectives support the development of a candidate therapeutic. The extent to which the preliminary data support the proposed phase of development, including clear efficacy in at least one appropriate ALS model, with adequate power and methods, and relevant physical, chemical and/or biological properties.
- **Clinical Impact:** Whether the proposed work will have significant clinical impact on the target population, including specific ALS subtypes. How well the steps to transition the study outcomes to therapeutic application are outlined.
- **Research Strategy:** How well the project's specific aims and feasibility support the development of a candidate therapeutic and meet the intent of the award mechanism. The extent to which appropriate mechanism-specific biomarkers are included or plans for their development are outlined, and how these biomarkers will indicate target engagement, pharmacodynamics, or predict therapeutic effectiveness in individual patients or subgroups.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, of which, Research Strategy and Feasibility is the most important, followed by criteria of equal importance:

- **Research Strategy and Feasibility**
    - How well the study 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 studies are designed to achieve reproducible and rigorous results, the potential pitfalls and problem areas are identified, and alternative methods and approaches are addressed.
    - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether specific repository(ies) are named where data and research resources arising from the project will be stored.
    - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study, or whether the justification for a single-sex study is sufficiently strong.

    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 modifications and/or formulations of potential delivery systems are for the outlined chemical synthetic pathways associated with the lead compound(s).

    For studies involving animal research:

    - Whether the ALS animal study (or studies) is designed to achieve the objectives, including the choice of model and incorporation of ALS model guidelines, model group size, and endpoints/outcome measures to be used.
    - For efficacy studies, whether the drug dose(s) and route(s) of administration are justified.
    - Whether the proposed ALS animal study (or studies) is designed to achieve reproducible and rigorous results, including controls, statistical methods used, sample size estimation, blinding, randomization and data handling.

- **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.
  - How well the project's objectives support the development of a candidate therapeutic. Candidate therapeutics that already have been granted an IND are not appropriate for the TDA.
  - Whether the lead compound(s) is already in hand.
- **Transition Readiness**
  - 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.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- **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.
  - Whether the knowledge, information, products, or technologies gained from the proposed research is of significance to Service Members, Veterans and/or their Families.

- If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **Personnel**
  - The appropriateness of the study team's expertise and the level of effort committed to ensure the successful execution of the proposed work.
  - The suitability of the research team's backgrounds and expertise for developing the proposed product.

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**:

- **Budget**
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - The extent to which the scientific environment and the quality and level of institutional support are appropriate for the successful execution of the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

6.2.3. 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 peer reviewers
- Relevance to the priorities of the FY26 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

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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 the Code of Federal Regulations, Title 2, Part 200.1 (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 the SAM.

An applicant organization may review the 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

8. Post-Award Requirements

8.1. 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.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local IACUC, Institutional Review Board (IRB) or Ethics Committee (EC) review.

8.2. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical progress 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, using the template available on eBRAP, must be submitted with the final progress report.

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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

Unless otherwise restricted, changes in the 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.

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Preproposal Narrative is missing.

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

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY26 ALSRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b)

cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.

- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.
- Animal Research Plan (Attachment 9) is missing, *for applications proposing animal research.*
- The invited application proposes a different research project than that described in the pre-application.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP 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"	☐
Biomarker Statement – Attachment 6, upload as "Biomarker.pdf"	☐
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐
Transition Plan – Attachment 8, upload as "Transition.pdf"	☐
Animal Research Plan – Attachment 9, upload as "AnimalPlan.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 10, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 11, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐
Research & Related Budget	☐
Project/Performance Site Location(s)	☐
Research & Related Subaward Budget Attachment(s) ***(if applicable)***	☐

Appendix 2. Acronym List

ALS	Amyotrophic Lateral Sclerosis
ALSRP	Amyotrophic Lateral Sclerosis Research Program
ARRIVE	Animal Research: Reporting of In Vivo Experiments
BEST	Biomarkers, EndpointS, and Other Tools
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
COU	Context of Use
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IND	Investigational New Drug
IRB	Institutional Review Board
LC-MS	Liquid Chromatography-Mass Spectrometry
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PI	Principal Investigator
R&D	Research and Development
RPPR	Research Performance Progress Report

SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
TDA	Therapeutic Development Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs