Program Announcement for the Defense Health Agency

Amyotrophic Lateral Sclerosis Research Program

Clinical Outcomes and Biomarkers Award

Funding Opportunity Number: HT942526ALSRPCOBA

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) Clinical Outcomes and Biomarkers Award (COBA) supports the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials in amyotrophic lateral sclerosis (ALS). Projects can be relevant to a specific therapy, a class of therapeutics, or to a specific ALS subtype (such as a particular genetic mutation) and do not have to broadly apply to all patients.

Distinctive Features: To meet the intent of the funding opportunity, applications may address ***clinical biomarkers and/or clinical outcomes***. This may include the identification, development, and/or validation of promising biomarkers for ALS, which may include, but are not limited to susceptibility/risk, diagnostic, monitoring/disease progression, prognostic, predictive, response, or safety biomarkers. Clinical Outcomes projects may focus on the identification, development, and/or validation of clinician-, observer-, or patient-reported, and/or performance outcome measures for ALS. Projects may include the optimization of current outcome measures already in use.

Applications may utilize digital health measures, including wearable devices, smart-phone sensors, video or voice recordings, imaging studies, or other devices which record disease-relevant physiological data and/or outcomes.

Community Collaboration is an important element of the FY26 ALSRP COBA. Applicants will be expected to articulate how the proposed research question or study design was informed by the ALS lived experience community.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $7.0 million (M) to fund approximately seven COBA applications with total cost caps of $1.0M 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: HT942526ALSRPCOBA

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.

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 Clinical Outcomes and Biomarkers Award (COBA) mechanism was first offered in FY24. Since then, 58 Clinical Outcomes and Biomarkers Award applications were received, and 12 were recommended for funding.

3.2. Intent of the Clinical Outcomes and Biomarkers Award

The FY26 ALSRP COBA supports the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials in ALS. Projects can be relevant to a specific therapy, a class of therapeutics, or to a specific ALS subtype (such as a particular genetic mutation) and do not have to broadly apply to all patients. ***Biomarkers should be specific for ALS, rather than generic*.** The FY26 ALSRP is particularly interested in studies that compare ALS-specific biomarkers to its mimics.

Research may include, but is not limited to:

- Target engagement biomarkers.
- Pharmacodynamic biomarkers to measure the biological effect of an investigational therapeutic.
- Predictive/cohort-selective biomarkers that indicate whether a specific therapy is likely to be effective in an individual patient or patient subgroup.
- Diagnostic, prognostic, phenotypic conversion, and/or disease progression biomarkers. ***Diagnostic biomarkers that help distinguish ALS from other clinical mimics are of particular interest to the FY26 ALSRP.***
- Clinician-, observer-, patient-reported, and/or performance outcomes to better support clinical trial success metrics.
- Defining ALS subtypes using patient-based resources, such as biosamples and/or digital data elements linked to rigorous molecular and clinical data.

- Addition of the collection of biospecimens, outcome measures, or digital health data to an on-going or planned clinical trial.
- Correlation of clinical-trial related data (e.g., analysis of biosamples, imaging, and/or digital health data) with clinical outcomes or responses to therapies.

3.2.1. Key Elements for the COBA

Applications should address clinical biomarkers and/or clinical outcomes as described below:

Clinical Biomarkers: Identification, development, and/or validation of promising biomarkers for ALS. Biomarkers may include, but are not limited to susceptibility/risk, diagnostic, phenotypic conversion, monitoring/disease progression, prognostic, predictive, response, or safety biomarkers.

Clinical Outcomes: Identification, development, and/or validation of clinician-, observer-, or patient-reported, and/or performance outcome measures for ALS. Projects may include optimization of current outcome measures already in use.

Both clinical biomarkers and clinical outcomes research projects may utilize digital health measures, including wearable devices, smart-phone sensors, video or voice recordings, imaging studies, or other devices which record disease-relevant physiological data and/or outcomes.

Use of existing well-characterized and highly curated clinical resources is encouraged. Examples of patient-based ALS resources include ongoing or completed clinical trial datasets, biorepositories of clinical specimens, registries (e.g., Centers for Disease Control and Prevention National ALS Registry and/or Biorepository, large omics datasets, patient-reported outcomes, digital biomarker datasets, and databases of clinical data and/or metadata. Active-duty military and/or Veteran patient populations or resources should be considered. Collaboration with the DOW and/or U.S. Department of Veterans Affairs (VA) is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI. A list of suitable ALS-specific resources can be found on the ALSRP web page. Other resources used must include an adequate description of repository parameters and mechanisms for broad access.

A strong Data and Research Resources Sharing Plan is an important component for a successful COBA application.

Studies prospectively enrolling patients to collect biospecimens and/or clinical or digital data are permitted. The proposed studies may be stand-alone or add-on noninterventional clinical research studies. However, clinical trials are not allowed under this mechanism.

Employing community collaborations to optimize research impact: Research funded by the FY26 ALSRP COBA should be responsive to the needs of people with ALS, their families and/or their care partners. ***Pre-applications and applications are required to incorporate Community Collaboration*** to provide advice and consultation throughout the planning of the research project.

Applications investigating clinical outcomes, proposing prospective biospecimen collection, or enrolling patients must also integrate the community collaborator(s) in the implementation and execution of the research project.

The Community Collaboration partners should have meaningful and ongoing input on all aspects of projects that involve prospective recruitment, which can include needs assessment,

planning, research intervention design, implementation, evaluation and dissemination. These collaborations are expected to facilitate accessible, efficient and humane research approaches. Interactions with other team members should be well-integrated and ongoing, and not limited to attending seminars and semi-annual meetings. Examples of Community Collaborations include (only one collaboration is required):

- **Person(s) Living with ALS, Family Member(s) and/or Caregiver(s):** The research team includes persons with ALS, their family members, or caregivers (past or present) as project advisors who will provide advice and consultation throughout the planning and implementation of the research project.
- **Partnership with a Community-Based Organization:** The research team establishes a partnership with at least one community-based organization that provides advice and consultation throughout the planning and implementation of the research project. Community-based organizations may include advocacy groups, service providers, policymakers, or other formal organizational stakeholders.
- **Community Advisory Board:** A community advisory board is composed of multiple community stakeholders and can take many forms, from a board of people living with ALS, their family members, or caregivers to a coalition of community-based organizations, or any combination thereof. As with people living with ALS and organizational partners, the community advisory board provides advice and consultation throughout planning and implementation of the research project.

For projects proposing the use of 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.

A description of the biomarker category and intended context of use (COU), including regulatory considerations for use in ALS clinical trials or clinical practice, is an important component. For further information on biomarker types, qualifications, and use in ALS clinical trials, it is recommended that applicants consult the following resources:

- "National Institute of Neurological Disorders and Stroke (NINDS) Biomarker Program," National Institutes of Health (NIH) https://www.ninds.nih.gov/current-research/focus-tools-topics/focus-biomarkers-research.
- "U.S. Food and Drug Administration (FDA) Biomarker Qualification Program," FDA, https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/biomarker-qualification-program.
- 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 digital health guidance guidelines, it is recommended that applicants consult the following resources:

- Caroline Franck Perrin et al, "iCHECK-DH: Guidelines and Checklist for the Reporting on Digital Health Implementations," *Journal of Medical Internet Research* 25 (2023): e46694, https://doi.org/10.2196/46694.
- Srikanth Vasudevan et al, "Digital Biomarkers: Convergence of Digital Health Technologies and Biomarkers," *NPJ Digital Medicine* 5, no. 1 (2022): 36, https://doi.org/10.1038/s41746-022-00583-z.

3.2.2. Other Important Considerations for the COBA

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 mutually inclusive 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, the 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.

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 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 **$1.0M**. 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 two scientific/technical meetings per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the ALSRP Clinical Outcomes and Biomarkers 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:

  - **Use of Clinical ALS Resources:** Summarize how the project will prospectively collect clinical samples/data or will leverage existing ALS repositories and/or datasets.
  - **Biomarker Development:** Describe the biomarker category and intended COU in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice. Reference the FDA Biomarker Qualification Program for COU definitions and examples. Concisely state the project's hypothesis, specific aims, and feasibility of the scientific approach. Provide scientific rationale of how the research will support the project objectives or hypothesis, specific aims, and feasibility.
  - **Data Sharing:** Describe plans to make results or outcomes available for use by others. Include considerations of existing, publicly available and curated ALS repositories.
  - **Clinical Impact in the Intended Population:** Explain how the proposed project will advance the development and/or validation of biomarkers for disease progression or prognosis assessment; or how the project is relevant to a specific therapeutic (or class of therapeutics) or to a specific type of ALS (such as a particular genetic mutation) with potential to better define subsets. Identify community collaboration partner(s), and describe how they will provide advice and consultation throughout the planning and implementation of the research project.

- **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 for 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.
    - **Background and Scientific Rationale:** Explain why the proposed research is important and how it addresses clinical biomarkers and/or clinical outcomes. Describe the scientific rationale on which the proposed work is based. Demonstrate feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning and presentation of published or unpublished preliminary data. Preliminary data should be clearly described with statistics. Strong rationale and feasibility, showing proof of concept and clinical relevance of the proposed research, are critical.
    - **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, community collaborator). ***Inclusion of a biomarker interpretation expert is highly encouraged.***

- **For Clinical Outcome Studies:** Describe the clinician-, observer-, or patient-reported outcome with respect to ALS biology or clinical relevance. Describe how easily this outcome may be incorporated into future clinical trials of a proposed therapeutic.
- **For Clinical Biomarker Studies:** Describe feasibility of the biomarker with respect to ALS biology or clinical relevance. Clearly describe the biomarker category and intended COU in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice. Reference the FDA Biomarker Qualification Program for COU definitions and examples. Describe how the proposed study has the potential to lead to major advancements in ALS treatment or to better define subsets for clinical treatment. The inclusion of a decision-tree diagram that explicitly illustrates the application of the biomarkers and includes the anticipated actions to be taken based on the biomarker results is recommended. Describe how easily and reliably the biomarkers may be implemented in eventual clinical trials of a proposed novel therapeutic.
- **Research Strategy and Specific Aims:** Describe the experimental design, methods, and statistical plan and analyses, including appropriate controls and endpoints, in sufficient detail. The statistical plan should be appropriate for the variables being measured. A biostatistician may be recruited to peer review the application.
  - Describe the type of ALS patient specimen, patient data and/or existing cohort being leveraged and explain how the resource is appropriate for the objectives of the study.
  - Provide statistical considerations to demonstrate that the work is appropriately powered.
  - Applications involving artificial intelligence should include details regarding the specific platforms and approaches they intend to implement.
  - If recruiting human subjects for patient specimen collection, describe the study population and include a detailed plan for recruitment provided additional details in Attachment 12). ***This award may not be used to conduct clinical trials.***
  - Describe whether the population selected to participate in the study stands to benefit from the knowledge to be gained as a result of the proposed research, how the level of risk to study participants is minimized, and what safety monitoring and reporting measures are taken for the level of risk.
  - Concisely explain the project's specific aims to be funded by this award. Describe how data will be collected, handled, and analyzed (including a detailed statistical plan) in a manner consistent with the study objectives.
  - Briefly describe plans to make results or outcomes available for use by others. **Details of data and resource sharing should be provided in Attachment 10, Data and Research Resources Sharing Plan.**
  - Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Describe potential challenges and alternative strategies where appropriate.

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. There is not a standardized 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 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.

- **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.
  - **Impact:** Explain how the proposed project has the potential to lead to critical discoveries or major advancements in clinical outcomes, disease progression markers for a specific therapeutic or class of therapeutics or for a specific type of ALS (such as a particular genetic mutation) to better define subsets.
  - **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 type(s) of ALS patients will the research help and how will it help them?
  - What are the potential clinical applications, benefits and risks of the anticipated outcomes?
  - What is the projected time it may take to achieve a patient-related outcome?
  - What are the likely contributions of this study to improve treatments and find cures for ALS?
  - What is the potential benefit of the proposed study and the anticipated outcomes to Service Members, Veterans and/or 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 either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

- **Attachment 6: Letter(s) Confirming Access to Population(s) or ALS Patient Resource(s), if applicable (one-page limit per letter is recommended): Upload as "Access.pdf".** Provide a letter of support signed by the appropriate institution official who has the authority to confirm access to the proposed population(s) or resource(s) necessary to carry out the study. Resources include, but are not limited to, patient biosamples, clinical data, existing cohorts or other components of current clinical care.

- **Attachment 7: Clinical Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe how the proposed work will impact ALS clinical care. The statement should address the points outlined below written ***in a manner that is readily understood by readers without a background in science or medicine.*** Specifically highlight how the clinical biomarker development and/or validation effort will:
  - Advance the development of biomarkers for disease progression, phenotypic conversion detection, or prognosis assessment; or is relevant to a specific therapeutic (or class of therapeutics) or to a specific type of ALS (such as a particular genetic mutation) with potential to better define subsets.
  - Lead to meaningful improvements in patient care.
  - Create new and outstanding shared resources and/or enhance the value of existing research resources through biosamples, data, and information sharing.
  - 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 the short-term or long-term potential for significant reduction or elimination of the disproportionate effects of ALS on specific populations.
  - 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 bulleted to emphasize the main study goals. Inclusion of a simple diagram of the proposed study, if plausible, is encouraged.
- **Attachment 8: Community Collaboration Plan (no page limit): Upload as "Community.pdf".** Refer to Section 3.2.2 for more details regarding the Community collaboration requirement. This attachment must be written ***in a manner that will be readily understood by readers without a background in science or medicine.***
  - **Community Collaboration Statement:** Describe the collaborative research approach that will be used (e.g., lived experience consultant or a partnership with community-based organization or a community advisory board). Detail when and how the approach will be used within the research project; how the community collaborator(s) will be engaged throughout the study; how input will be meaningfully incorporated into the research design, execution, and dissemination; and explain how this best serves the ALS community.
  - Include the name of at least one community partner—person(s) with ALS, family member(s) and/or care partner(s), representative of a community-based organization or community advisory board—who will provide advice and consultation throughout the planning and implementation of the research project.
  - Describe any training, co-learning, or capacity-building activities that will be provided to both scientific researchers and community partners on collaborative research approaches, decision-making and equitable participation.
  - **Letters of Community Collaboration (two-page limit per letter is recommended):** Provide a letter signed by each community collaborator confirming their role and commitment to participate on the research team and throughout the research effort. The letter should include a mention of why the qualifications and/or background of the individual will benefit the proposed research project. If a community-based organization/advisory board will be engaged, the letter of

commitment should be signed by BOTH the organization point of contact and the organization's leadership endorsing the collaboration.

- **Describe how feedback from the ALS community will be integrated** into the progression of this research and continued development of the intervention.

- **Attachment 9: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable. A Regulatory Compliance or Technology Transfer Specialist may be recruited to peer review the application.

  - State the clinical outcome and/or biomarker name(s).

  For clinical outcomes and/or biomarkers that do not require regulation by a Regulatory Agency:

  - Provide documentation supporting this conclusion. The response must include:
    - A clear explanation of why the biomarker or clinical outcome measure does not meet criteria for regulation under applicable U.S. federal regulations (e.g., IND, IDE, device regulations, laboratory-developed test oversight, or biomarker qualification programs).
    - Citation of relevant statutory or regulatory authority (e.g., applicable sections of 21 CFR or equivalent international regulations).
    - Clarification of the intended use of the measure (exploratory, enrichment, safety monitoring, supportive endpoint, surrogate endpoint, etc.) and confirmation that this intended use does not trigger regulatory oversight.
    - If applicable, provide documentation of regulatory consultation (e.g., written communication with FDA or regulatory counsel) supporting this determination.

  For clinical outcomes and/or biomarkers that require regulation by a Regulatory Agency:

  - Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned indication/label. Include, as appropriate, a description of the regulatory application submission strategy to include milestone dates, regulatory consultant engagements, and any relevant partners. The plan must clearly articulate how the proposed work advances the asset toward regulatory approval, clearance, or qualification. Include:
    - Describe the development stage at project start and the anticipated stage at project completion.
    - State whether the clinical outcome and/or biomarker is FDA-approved, -licensed, or -cleared, and marketed in the United States. If marketed in the United States, state the label indication. State whether the proposed research involves a change to the approved label indication.
    - If the clinical outcome and/or biomarker is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and when an application to a Regulatory Agency will be submitted.
    - State the applicable regulatory pathway (e.g., IND, IDE, De Novo, biomarker qualification program, international equivalent, or other). Provide a regulatory submission strategy for the performance period with anticipated milestone dates.

- If the proposed research aligns with an ongoing or planned clinical trial for which an IND or IDE (or international equivalent) is required, ***the regulatory application must be submitted to the FDA or relevant international regulatory agency prior to the FY26 ALSRP COBA application submission deadline.*** Provide the date of submission, the application number and a copy of the FDA/international regulatory agency letter acknowledging the submission. If available, provide a copy of the communication from the FDA/international regulatory agency indicating the IND/IDE/regulatory application is active/safe to proceed. If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- **Attachment 10: Data and Research Resources Sharing Plan (three-page limit): Upload as "Resources.pdf".** Describe how data and resources generated during the performance of the project will be shared with the research community. Include plans and timelines for making raw data available in existing, publicly available, curated ALS repositories/data platforms or other resources with relevant repository parameters and mechanisms for broad access. A list of suitable resources can be found on the ALSRP web page. Detail the organizational and technical capabilities sufficient to share project data in a timely manner. *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).* Provide a plan for resolving intellectual and material property issues among participating organizations, if applicable. 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. 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.

  Do not submit a copy of the 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 11: Progression Plan (four-page limit): Upload as "Progression.pdf".** All applicants should contemplate and provide a plan outlining a practical trajectory to transition the research to full clinical implementation, and how this will ultimately translate to benefits for the intended recipients. Applicants should identify **the immediate next logical steps following the period of performance** and consider how those steps would be successfully achieved. A Regulatory Compliance or Technology Transfer Specialist may be recruited to peer review the application.

  – Describe the **immediate next logical step** proposed to progress the intervention to the next phase of development (clinical trials, commercialization, and/or delivery to the civilian or military market) after successful completion of the award. Include:

    - The timeline needed, with defined milestones, for that next step. This should include:

      - A sequenced development pathway
      - Defined regulatory inflection points

- ❖ Realistic time-to-execution assumptions
- ❖ Alignment with standard development paradigms (e.g., IND, Phase 1/2, End of Phase 2 meeting, Phase 3)

- If this step is immediately executable for clinical use, describe what is needed to implement. If another study is required, describe why this additional study is needed and whether that will bring the outcomes to a stage ready to execute and implement.
- Describe the scientific, technical, and/or regulatory requirements needed to advance the research findings, such as Good Manufacturing Practices (GMP) manufacturing readiness, analytical validation, assay reproducibility, device classification analysis, etc. Include steps necessary for regulatory approval, as applicable.
- Describe the specific collaborations, infrastructure, and external resources that will be leveraged to advance the intervention to the next stage of development or clinical implementation. Identify named or planned partners (e.g., clinical trial sites, contract research organizations, commercial partners, manufacturing organizations, regulatory consultants, clinical guideline committees, dissemination/training entities), and define their responsibilities and contribution to milestone achievement. Detail the current and anticipated intellectual property position, including ownership, patent status, freedom-to-operate considerations, licensing strategy, and commercialization pathway. If applicable, describe formal or planned agreements (e.g., Memorandums of Understanding, option agreements, sponsored research agreements). Applicants should document engagement with their Technology Transfer Office (or equivalent) and summarize the commercialization and IP strategy supporting progression.

- **Attachment 12: Population Statement, if applicable (one-page limit): Upload as "Population.pdf".** For clinical research studies or studies recruiting human subjects for patient specimen collection, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Describe how the research project will reduce disparities among high-risk groups and patients with limited access to clinical care and resources. Discuss how the project could, whether in the short-term or long-term, lead to significant reduction or elimination of the disproportionate effects of ALS on specific populations and reduce health inequity. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2). *Studies utilizing previously collected human biospecimens/datasets or resources that cannot be linked to a specific individual, sex, ethnicity, or race are exempt from this requirement. If an application is adding an aim to an existing clinical trial to conduct biosample collection and biomarker analysis, use of the patients enrolled in that trial is expected and the study potentially may not include diverse populations. These applications are exempt from this requirement.*
- **Attachment 13: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 14: 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

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 HT942526ALSRPCOBA from Grants.gov or eBRAP, depending on which submission portal will be used.

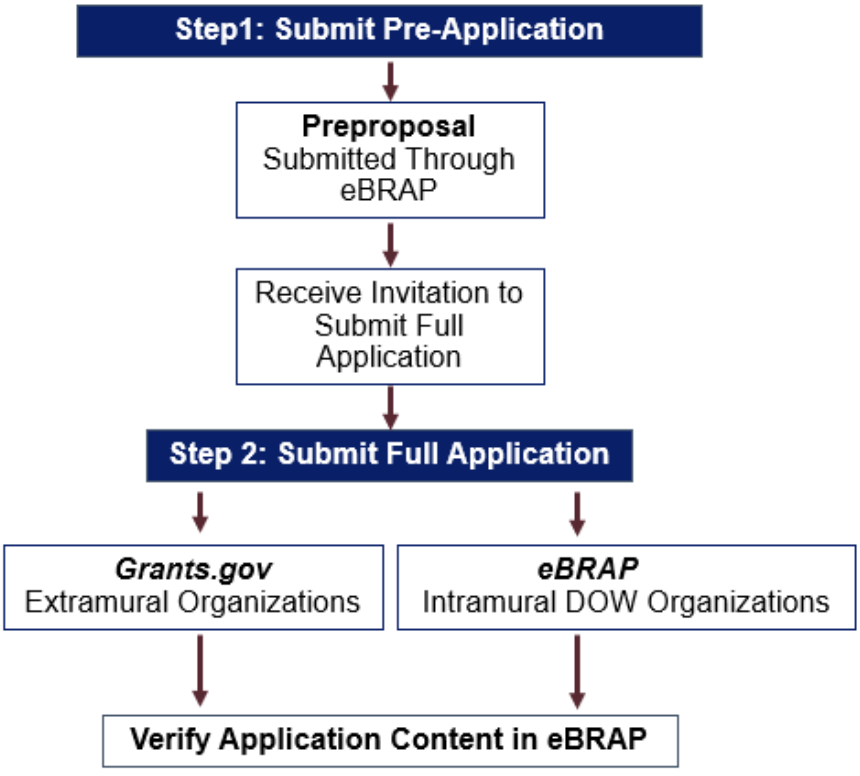
5.2. Unique Entity Identifier and System for Award Management

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:

- **Use of Clinical ALS Resources:** Whether the project will prospectively collect clinical samples/data or will leverage existing ALS repositories and/or datasets.
- **Biomarker Development:** How well the development and/or validation of clinical outcomes and biomarkers to enrich clinical trials are described. How well the biomarker category and intended COU in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice, are described. How well the scientific rationale supports the project objectives or hypothesis, specific aims and feasibility. Whether the required samples, data, or other resources exist or are feasible to obtain from an existing cohort.
- **Data Sharing:** Whether plans to make results or outcomes available for use by others (including considerations of existing, publicly available, curated ALS repositories) are described and appropriate.
- **Clinical Impact in the Intended Population:** Whether the proposed research meets the intent of the funding opportunity. To what degree the proposed study will advance the

development and/or validation of biomarkers for disease progression, phenotypic conversion detection, or prognosis assessment; or is relevant to a specific therapeutic (or class of therapeutics) or to a specific type of ALS (such as a particular genetic mutation) with potential to better define subsets. If outcome measures are the project's focus, to what extent the study will lead to meaningful improvements in clinical outcome measures. Whether the pre-application identifies a community collaborator.

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 biomarker category and intended COU in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice, are described; and to what extent the intended COU is supported by the study objectives.
  - How well the experimental design, methods, statistical plan and analyses are developed.
  - How well statistical considerations demonstrate that the work is appropriately powered, including appropriate controls and endpoints.
  - The extent to which data will be collected, handled, and analyzed in a manner consistent with the study objectives and statistical plan.
  - How well the studies are designed to achieve reproducible and rigorous results, the potential pitfalls and problem areas are identified, and the alternative methods and approaches are addressed.
  - How well the application describes future plans and opportunities for the eventual validation and independent replication of results.
  - 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.
  - If applicable, how well the recruitment process is outlined and the feasibility of statistical outcomes from these additional data.
  - If applicable, how well access to the ALS patient specimen, patient data, and/or existing cohort is described and to what extent the resource is appropriate for the objective of the study.
- **Scientific Rationale**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of published literature, logical reasoning, and presentation of published or unpublished preliminary data.
- **Clinical Impact**
  - If the project successfully achieves its aims, to what extent the clinical outcome and/or biomarker development and/or validation has the potential to change clinical care practices and patient management in ALS.
  - Whether the proposed clinical outcome and/or biomarker will lead to meaningful improvements in ALS clinical care and/or clinical trials by better predicting therapeutic

response, measuring target engagement, defining ALS subtypes, detecting phenotypic conversion, measuring disease progression, or assessing prognosis.

- How easily the outcome measure could be incorporated into ALS clinical care and/or clinical trials.
- 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, how well the short-term or long-term potential for significant reduction or elimination of the disproportionate effects of ALS on specific populations is addressed.
- 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.
  - How well the input of the Community Collaborator (e.g., person with ALS, family member and/or caregiver, representative of a community-based organization) is meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
- **Regulatory Strategy and Progression Plan**
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight or includes a well-described regulatory strategy and product development plan.
  - To what extent the regulatory strategy and product development plan are well-described and appropriate to support the product indication or product label change, if applicable.
  - To what degree the immediate next logical steps proposed to progress the intervention to the next phase of development, after successful completion of the award, are realistic and appropriate.
  - To what degree the collaborations and other resources intended to help advance the research outcome(s) are established and/or achievable.
  - The extent to which ownership rights and access to intellectual property necessary for the development and/or commercialization of the proposed products or technologies are addressed and planned for.
- **Data and Research Resources Sharing Plan**
  - How well the plan to share new biosamples, datasets, novel tools, and/or analyses broadly available for use by others is described.
  - Whether the proposed plan for data sharing considers existing, publicly available, curated ALS repositories/data platforms, or other resources with relevant repository parameters and mechanisms for broad access to data and samples.
  - Whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner.

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, to also include progression feasibility

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 Institutional Animal Care and Use Committee (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.

PHS Inclusion Enrollment Reporting *(required for research proposing clinical research)*: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

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 or 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 invited application proposes a different research project than that described in the pre-application.
- 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.

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"	☐
Letter(s) Confirming Access to Population(s) or ALS Patient Resource(s) – Attachment 6, upload as "Access.pdf"	☐
Clinical Impact Statement – Attachment 7, upload as "Impact.pdf"	☐
Community Collaboration Plan – Attachment 8, upload as "Community.pdf"	☐
Regulatory Strategy – Attachment 9, upload as "Regulatory.pdf"	☐
Data and Research Resources Sharing Plan – Attachment 10, upload as "Resources.pdf"	☐
Progression Plan – Attachment 11, upload as "Progression.pdf"	☐
Population Statement – Attachment 12, upload as "Population.pdf"	
Representations ***(Grants.gov submissions only)*** **– Attachment 13, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 14, upload as "IGBudget.pdf"**	☐
Additional Application Materials	
Research & Related Personal Data	☐
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) Form	☐
Research & Related Subaward Budget Attachment(s) Form ***(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
COBA	Clinical Outcomes and Biomarkers Award
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 Practices
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service

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
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs