

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

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Amyotrophic Lateral Sclerosis Research Program**

**Clinical Outcomes and Biomarkers Award**

**Announcement Type: Modified**

**Funding Opportunity Number: HT942524ALSRPCOBA**

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

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

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

*This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

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

#### II.A.1. FY24 ALSRP Clinical Outcomes and Biomarkers Award Focus Areas

To meet the intent of the funding opportunity, applications must address ONE or BOTH of the following focus areas:

**Clinical Biomarkers:** Identification, development, and/or validation of promising biomarkers for ALS. Biomarkers may include, but are not limited to susceptibility/risk, diagnostic, 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 focus areas are permitted to 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.

### II.B. Award Information

The FY24 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.

Research may include, but is not limited to:

- Target engagement biomarkers.
- Objective pharmacodynamic biomarkers to measure the biological effect of an investigational therapeutic.

- Predictive/cohort-selective biomarkers that indicate whether a specific therapy will be effective in an individual patient or patient subgroup.
- Diagnostic, prognostic, or disease progression.
- Validate clinician-, observer-, patient-reported and/or performance outcomes to better support clinical trial success metrics.
- Define ALS subtypes using patient-based resources to link biosamples and/or digital data elements to rigorous molecular and clinical data.
- Realize improved strategies that better measure disease progression for people living with ALS.
- Augment biospecimens, outcome, or digital health data to an on-going clinical trial.
- Correlate clinical-trial related data (e.g., biosample, imaging, digital health data) with clinical outcomes or responses to therapies.

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; <https://www.cdc.gov/als/Default.html>), large omics datasets, patient-report 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. A list of suitable resources can be found on the ALSRP web page (<https://cdmrp.health.mil/alsrp/resources/ALSRPResources>). Other resources may be used, provided they have an adequate description of repository parameters and mechanisms for broad access.

***Employing community collaborations to optimize research impact:*** Research funded by the FY24 ALSRP COBA should be responsive to the needs of people with ALS, their families, and/or their care partners. ***Applications proposing prospective biospecimen or participant enrollment are required to name at least one community partner*** (e.g., person with ALS, family member and/or caregiver, representative of a community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project. All research teams applying to the FY24 ALSRP COBA are *encouraged* to establish and utilize effective and equitable collaborations and partnerships with community members to maximize impact potential of the proposed research.

Scientific researchers and community members will collaborate and contribute equitably on all aspects of the project, which may 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, not limited to attending seminars and semi-annual meetings. Examples for implementing collaborative research approaches include:

- **Person Living with ALS, Family Member, and/or Caregiver:** The research team includes a person with ALS, their family member, or caregiver (past or present) as a project advisor 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 partnerships 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 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.

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:

- BEST (Biomarkers, EndpointS, and other Tools) Resource.  
<https://www.ncbi.nlm.nih.gov/books/NBK326791/>
- National Institute of Neurological Disorders and Stroke (NINDS) Biomarker Program.  
<https://www.ninds.nih.gov/current-research/focus-tools-topics/focus-biomarkers-research>
- U.S. Food and Drug Administration (FDA) Biomarker Qualification Program.  
<https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/biomarker-qualification-program>
- FDA Guidance Document – “Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry.” September 2019. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/amyotrophic-lateral-sclerosis-developing-drugs-treatment-guidance-industry>
- Verber NS, Shephard SR, Sassani M, et al. 2019. Biomarkers in motor neuron disease: A state of the art review. *Frontiers in Neurology* 10:291.  
<https://www.frontiersin.org/articles/10.3389/fneur.2019.00291/full>
- van den Berg LH, Sorenson E, Gronseth G, et al. 2019. Revised Airlie House consensus guidelines for design and implementation of ALS clinical trials. *Neurology* 92(14):e1610-e1623. <https://n.neurology.org/content/92/14/e1610>

- Benatar M, Boylan K, Jeromin A, et al. 2016. ALS biomarkers for therapy development: state of the field and future directions. *Muscle Nerve* 53(2):169-182.  
<https://doi.org/10.1002/mus.24979>

***Studies prospectively enrolling patients to collect biospecimens and/or data are allowed***, such as stand-alone or add-on non-interventional clinical research studies to prospectively collect biosamples and/or clinical or digital biomarker data. However, clinical trials are not allowed under this mechanism.

### **Additional Considerations:**

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

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

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

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

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

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 ALSRP COBA Award should not exceed **\$750,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

*The CDMRP expects to allot approximately \$6.1M to fund approximately five Clinical Outcomes and Biomarkers Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

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

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

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

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

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

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

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

Independent investigators at all career levels may be named by the organization as the Principal Investigator (PI) on the application.

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

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

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

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

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

## II.D. Application and Submission Information

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

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

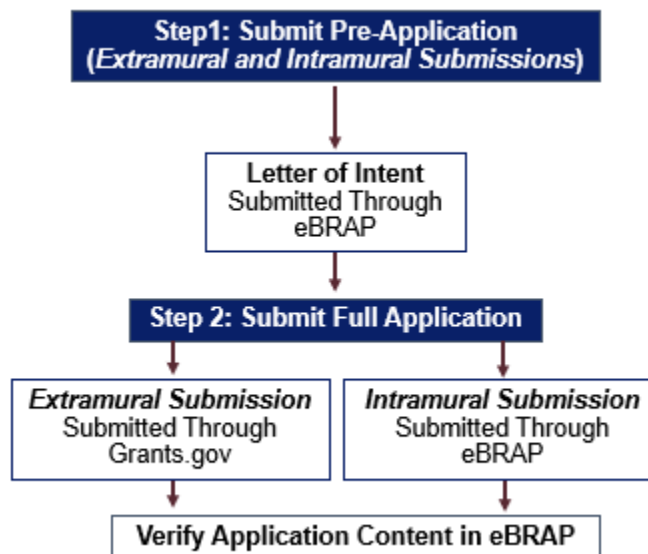
The CDMRP uses two portal systems to accept pre- and full application submissions.

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

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



### *Application Submission Workflow*



**Extramural Submission:** An application submitted by an [extramural organization](#) for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524ALSRPCOBA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

**Intramural Submission:** An application submitted by an [intramural DOD organization](#) for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524ALSRPCOBA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

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

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

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

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

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

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

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

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

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

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

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

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted, and provide the name(s) of the community collaborator(s), if applicable.

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

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

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

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

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

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

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

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

#### **(b) Attachments:**

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

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

Describe the proposed project in detail using the outline below.

- **Background and Scientific Rationale:** Explain why the proposed research is important and how it is addressing one or more of the FY24 ALSRP COBA Focus

Areas. Describe the scientific rationale on which the proposed work is based. Demonstrate logical reasoning and provide sound scientific rationale for the proposed project through a critical review and analysis of published literature. Provide sufficient data, published or unpublished, to support the feasibility of work proposed. It is important to describe studies showing proof of concept and clinical relevance.

- **Clinical Outcomes (if applicable):** Describe the self-reported, clinician, observer, or 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.
- **Clinical Biomarker Feasibility (if applicable):** Describe feasibility of the biomarker with respect to ALS biology or clinical relevance. Clearly describe the biomarker category and intended context of use in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice. Reference the FDA Biomarker Qualification Program for Context of Use (COU) definitions and examples <https://www.fda.gov/drugs/biomarker-qualification-program/context-use>. 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 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 a proposed novel therapeutic.
- **Research Strategy and Specific Aims:** Describe the experimental design, methods, statistical plan and analyses, including appropriate controls and endpoints, in sufficient detail for analysis.
  - 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.
  - If human subjects will be recruited for patient specimen collection, describe the study population, and include a detailed plan for recruitment. ***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, what safety monitoring and reporting measures are taken for the level of risk.
  - Describe the strategy for the inclusion of women and minorities in the non-interventional clinical research study, appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and/or ethnicity, and an accompanying rationale for the

selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at

<https://ebrap.org/eBRAP/public/Program.htm>. *Additional details regarding diversity should be provided in [Attachment 8, Diversity Statement](#).*

- 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.
  - Describe plans to make results or outcomes available for use by others. *Details of data and resource sharing should be provided in [Attachment 11, Data and Research Resources Sharing Plan](#).*
  - Describe potential challenges and alternative strategies where appropriate.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (two-page limit per letter is recommended):** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable) (two-page limit per letter is recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Use of DOD/U.S. Department of Veterans Affairs (VA) Resources (if applicable):** Provide a signed letter of support confirming access for the entire period of performance to active-duty military population, VA patients, and/or VA/DOD resources, databases, or research space. Provide any details on arrangements or agreements required to access and publish data here.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

- **Background:** Present the scientific rationale behind the proposed research project and indicate how this addresses one or more of the Focus Areas.
- **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.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. *Do not duplicate the technical abstract.*

Provide background information necessary for readers without scientific or medical training to readily understand the rationale and feasibility of the proposed research project. The lay abstract should also clearly describe the scientific objective the project is designed to achieve. The lay abstract should be structured in accordance with the outline below:

- Describe the ultimate applicability of the research.
- What type(s) of ALS patients will it help and how will it help them?
- What are the potential clinical applications, benefits, and risks?
- What is the projected time it may take to achieve a patient-related outcome?
- What are the likely contributions of this study to improve treatments and find cures for ALS?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

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

- **Attachment 6: Letter(s) Confirming Access to Population(s) or ALS Patient Resource(s), if applicable (one-page limit per letter): 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. Specifically highlight how the clinical biomarker development effort will:
  - Lead to meaningful improvements in ALS clinical trials by better predicting therapeutic response, measuring target engagement, defining ALS subtypes, measuring disease progression, or assessing prognosis.
  - Lead to meaningful improvements in patient care.
  - Create new and outstanding clinical collaborations through information sharing.
- **Attachment 8: Diversity Statement (one-page limit): Upload as “Diversity.pdf”.** If human subjects will be recruited for patient specimen collection, describe how diversity and inclusion is addressed in the research project. 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. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. The Inclusion Enrollment Report form, Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under “Resources and Reference Material” at <https://ebrap.org/eBRAP/public/Program.htm>. *Studies utilizing previously collected human biospecimens/datasets or resources that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement and may submit “N/A” (to indicate not applicable) for this statement. 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 and may submit N/A for this statement.*
- **Attachment 9: Community Collaboration Plan (no page limit). Required for applications proposing prospective biospecimen or participant enrollment. Upload as “Community.pdf”.** Refer to [Section II.B](#) 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 at or around the eighth-grade level.*
  - **Community Collaboration Statement:** Describe the collaborative research approach that will be used (e.g., Lived experience consultant, partnership with community-based organization, community advisory board, co-researcher model). Detail when and how the approach will be used within the research project, how input will be meaningfully incorporated into the research design, execution, and dissemination, and explain how this best serves the ALS community.
  - Include the names of at least one community partner (person with ALS, a family member and/or caregiver, 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 members on collaborative research approaches, decision-making, and equitable participation.
  - **Letters of Community Collaboration (two-page limit per letter):** Provide a letter signed by each Community partner confirming their role and commitment to participate on the research team. The letter should include a mention of why the qualifications and 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 participating and the organization’s leadership endorsing the collaboration.
  - **Attachment 10: Progression Plan (three-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 what are **the next immediate logical steps following the period of performance** and consider how those steps would be successfully achieved.
    - Describe the **immediate next logical step** to 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. If this step is immediately executable for clinical use, describe what is needed next to implement. If another study is required, describe why this additional study is needed and whether that will bring the outcomes to stage ready to execute and implement.
      - Describe the scientific, technical, and/or regulatory requirements needed to advance the research findings. Include steps necessary for regulatory approval, as applicable.
      - Describe collaborations and other resources that will be used to help progress the continuity of research to the next stage of development or clinical implementation (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources). Include considerations of intellectual property, ownership rights, licensing, and commercialization plans, as applicable here. Applicants are encouraged to work with their Technology Transfer Office (or equivalent).
    - **Describe how feedback from the ALS community will be integrated** into the progression of this research and continued development of the intervention.

- **Attachment 11: Data and Research Resources Sharing Plan: 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 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 (<https://cdmrp.health.mil/alsrp/resources/ALSRPresources>). Detail the organizational and technical capabilities sufficient to share project data in a timely manner. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. The government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations. Note that this document may be used in programmatic review deliberations.
  - **Attachment 12: Representations (*Extramural Submissions Only*): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
  - **Attachment 13: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”. State the qualifications of the PI and key personnel to perform the described research project. Relevant ALS expertise is important. If the designated PI is an early-career investigator or an early-career physician-scientist, describe experience and accomplishments that demonstrate potential for developing a promising career in the field of ALS research.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
  - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch\_LastName.pdf”.
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
  - **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 13.

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

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

[application verification period](#). The full application cannot be modified once the application verification period ends.

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

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

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

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

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

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

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

The application’s direct costs budgeted for the entire period of performance should not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

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

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

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 ALSRP Clinical Outcomes and Biomarkers Award.

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

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

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

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

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

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

- **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 data.
  - If provided, how well the preliminary data support the rationale for the proposed research.
- **Research Strategy and Feasibility**
  - How well feasibility of the outcome or biomarker with respect to ALS biology or clinical relevance is described.
  - How well the biomarker category and intended Context Of Use (COU) in ALS therapy development, including regulatory considerations for use in ALS clinical trials or clinical practice, is 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 to demonstrate that the work is appropriately powered are addressed.
  - 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.
  - The extent to which data will be collected, handled, and analyzed (including a detailed statistical plan) in a manner consistent with the study objectives.
  - If applicable, how well the recruitment process is outlined and the feasibility of statistical outcomes from these additional data.
  - If applicable, how well diversity is addressed and the short-term or long-term potential for significant reduction or elimination of the disproportionate effects of ALS on specific populations.
  - How well the potential challenges and alternative strategies are identified.

- How well the application describes future plans and opportunities for eventual validation and independent replication of results.
- **Clinical Impact**
  - If the project successfully achieves its aims, how well the proposed clinical outcome and/or biomarker will impact clinical care.
  - Whether the proposed clinical outcome and/or biomarker will lead to meaningful improvements in ALS clinical trials by better predicting therapeutic response, measuring target engagement, defining ALS subtypes, measuring disease progression, or assessing prognosis. Outcome/biomarker development or data analysis may be relevant to a specific therapeutic or to a specific type of ALS (such as a particular genetic mutation) and *does not have to broadly apply to all patients*.
  - How well the proposed research will create new and outstanding clinical collaborations and information sharing.
- **Personnel**
  - How appropriate the composition, background, and levels of effort of the study team are for successful conduct of the proposed work.
  - How well the input of the community partner (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.
- **Data and Research Resources Sharing Plan**
  - How well the plan to share biosample/data collection and analyses that would be of broad interest to ALS therapy development 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**

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

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 ALSRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Appropriateness of the Data and Research Resources Sharing Plan

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

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of

confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD

animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

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

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

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

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

**PHS Inclusion Enrollment Reporting Requirement:** Enrollment reporting on the basis of sex/gender, race, and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in 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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent five-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

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

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

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

Phone: 301-682-5507

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

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

*Questions regarding Grants.gov registration and Workspace:*

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

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

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

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

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

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

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

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

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

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

- Pre-application was not submitted.

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

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

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

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

- An FY24 ALSRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the

development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 ALSRP Programmatic Panel members can be found at <https://cdmrp.health.mil/alsrp/panels/panels24>.*

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- Applications proposing prospective biospecimen or participant enrollment that do not name at least one community partner.

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

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

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

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

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

Full Application Components	Uploaded
<b>SF424 Research &amp; Related Application for Federal Assistance</b> (Extramural submissions only)	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> (Intramural submissions only)	<input type="checkbox"/>
<b>Attachments</b>	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Letter(s) Confirming Access to Population(s) or ALS Patient Resource(s) (if applicable) – Attachment 6, upload as “Access.pdf”	<input type="checkbox"/>
Clinical Impact Statement – Attachment 7, upload as “Impact.pdf”	<input type="checkbox"/>
Diversity Statement – Attachment 8, upload as “Diversity.pdf”	<input type="checkbox"/>
Community Collaboration Plan – Attachment 9, upload as “Community.pdf”	<input type="checkbox"/>
Collaboration Plan (if applicable) – Attachment 10, upload as “Progression.pdf”	<input type="checkbox"/>
Data and Research Resources Sharing Plan – Attachment 11, upload as “Resources.pdf”	<input type="checkbox"/>
Representations (Extramural submissions only) – Attachment 12, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 13, upload as “IGBudget.pdf”	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
<b>Research &amp; Related Budget</b> (Extramural submissions only) Include budget justification	<input type="checkbox"/>
<b>Budget</b> (Intramural submissions only) Include budget justification	<input type="checkbox"/>
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> (if applicable)	<input type="checkbox"/>

<b>Additional Application Components</b>	<input type="checkbox"/>
<b>Confidential Letters of Recommendation</b>	<input type="checkbox"/>

## **APPENDIX 1: ACRONYM LIST**

ALS	Amyotrophic Lateral Sclerosis
ALSRP	Amyotrophic Lateral Sclerosis Research Program
BEST	Biomarkers, EndpointS, and other Tools
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COBA	Clinical Outcomes and Biomarkers Award
COU	Context of Use
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NINDS	National Institute of Neurological Disorders and Stroke
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
PDF	Portable Document Format
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs