I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Multiple Sclerosis Research Program

Early Investigator Research Award

Announcement Type: Initial

Funding Opportunity Number: HT942524MSRPEIRA

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), July 24, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 7, 2024
- **Confidential Letters of Recommendation Submission Deadline**: 5:00 p.m. ET, October 14, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 14, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** January 2025

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) Multiple Sclerosis Research Program (MSRP) 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 MSRP in 2009 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the MSRP from FY09 through FY23 totaled $133.1 million (M). The FY24 appropriation is $20M.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY24 MSRP Early Investigator Research Award Focus Areas

To meet the intent of the funding opportunity, all applications submitted to the FY24 MSRP Early Investigator Research Award (EIRA) program announcement must address one or more of the following Focus Areas:

- **Central Nervous System Repair, Protection, and Regenerative Potential in MS**

  Supports innovative mechanistic studies and translational approaches to promote axonal protection, regeneration, or remyelination in MS and/or relevant experimental models of demyelination. Examples of acceptable studies include, but are not limited to:

  - Obstacles to repair and approaches to overcome and achieve remyelination. Factors to be considered include extrinsic or intrinsic factors (e.g., mechanical, sex, aging, inhibitory signaling), trophic and inhibitory factors, and lifestyle factors.
  - Cell-cell interactions within the central nervous system.
  - Epigenetic regulation of cells within the central nervous system.
  - Drugs, biologics, and cell-based therapies that target the central nervous system.
  - Identification of factors that promote protection and repair.
  - Innate immune-mediated mechanisms within the central nervous system.
  - Development of imaging and non-imaging outcome measures of repair.
  - Development of new models that reflect disease progression.

Note: Studies addressing developmental myelination, dysmyelination, basic mechanisms of demyelination, or peripheral immunomodulatory therapeutic strategies that limit tissue injury secondarily ***will not*** be considered for funding.

- **Correlates of Disease Activity and Progression in MS**

  Supports studies to identify and/or validate correlates of disease activity and progression using ***pre-existing*** specimens and/or data acquired from well-characterized, adequately controlled, and sufficiently powered patient cohorts.

  - Examples of acceptable cohorts for study include controlled clinical trials, observational studies, and registries.
  - Analyses may utilize existing clinical data and outcome measures, specimens, and/or imaging data.
  - Correlates include clinical outcome measures, patient self-reported measures, and imaging and non-imaging biomarkers.
  - Careful consideration should be given to potential confounders in the study population (e.g., disease-modifying therapies).

  Inclusion of information regarding the quality of the specimens, replication plan, assay validation, or context of use will be given special consideration.

  Note: The study must leverage ***pre-existing*** specimens and/or data that are available at the time of application submission; ongoing specimens and/or data collection from participants in the pre-existing cohort is allowed. However, the collection of new specimens and/or data or recruitment of new subjects is not permitted.

- **Biology and Measurement of MS Symptoms**

  Supports studies of MS symptoms, which may include pain, fatigue, depression, anxiety, incontinence, impaired mobility, and cognitive, motor, visual, or sexual dysfunction, etc. Examples of acceptable studies include, but are not limited to, the following:

  - Mechanisms underlying symptoms of MS.
  - Development of measurements for future interventional studies to alleviate symptoms.
  - Development and/or validation of outcome measures and tools for symptoms including wearables and/or remote data capture.
  - Observational studies on the prevalence or significance of symptoms including the contribution of comorbidities, lifestyle behaviors, and health disparities. Careful consideration should be given to potential confounders in the study population (e.g., disease-modifying therapies), controls, and/or accurate measures of symptoms.

Note: Studies of disease-modifying therapies that secondarily impact MS symptoms ***will not be*** considered for funding under this Focus Area.

- **Mechanisms Contributing to, or Associated with, MS Etiology, Prodrome, Onset, and Disease Course**

  Supports studies to identify various factors and their roles in MS etiology, prodrome, onset, activity, disease worsening, and progression. Examples of factors include, but are not limited to the following:

  - Infections (such as Epstein-Barr Virus and SARS-CoV-2) and/or vaccines
  - CNS innate immunity and compliment activation
  - Genetics and/or epigenetics
  - Environment
  - Comorbidities
  - Health behaviors
  - Demographics (including, but not limited to, sex, gender, race, ethnicity, age)
  - Socioeconomics and access to care.

II.A.2. Award History

The MSRP EIRA was first offered in FY21. Since then, 40 EIRA Award applications have been received, and 17 have been recommended for funding. The overall funding rate is 42.5%.

II.B. Award Information

The MSRP EIRA supports MS-focused research opportunities for individuals in the early stages of their careers, under the guidance of one or more designated Mentors. This opportunity allows for early-stage investigators to develop a research project, investigate a problem or question in MS research, and further their intellectual development as an MS researcher of the future. ***All application components for the EIRA are expected to be written by the Principal Investigator (PI), with appropriate direction from the Mentor(s).***

Key features of the award mechanism are as follows:

- **Principal Investigator:** The postdoctoral investigator is considered the PI of the application and must exhibit strong potential for, and commitment to, pursuing a career as an investigator at the forefront of MS research; however, the PI is not required to have previous MS research experience.
- **Mentor(s):** Applications must include at least one Mentor, appropriate to the proposed research project, who has experience in MS research and mentoring as demonstrated by a

record of active funding, recent publications, and successful mentorship. The primary Mentor can be a junior faculty member, in which case the PI is encouraged to include a secondary Mentor with a more robust track record in MS research and mentorship. The selected Mentor(s) should also demonstrate a clear commitment to the development of the PI toward independence as an MS researcher.

- **Researcher Development Plan:** The PI must outline an individualized, MS-focused Researcher Development Plan, which should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise that will enable the PI to successfully complete the proposed research project and foster the PI's development as an independent MS researcher. An environment appropriate to the proposed mentoring and research project must be clearly described, although any deficiencies of resources and/or mentorship at the PI's institution can be mitigated through collaboration(s) with other institutions. If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a secondary Mentor at the collaborating institution.

- **Research Project:** The proposed research project should address the critical needs of the MS community as outlined in the FY24 MSRP EIRA Focus Areas above. The scientific rationale and experimental methodology should demonstrate in-depth analysis of the research problem presented. The feasibility of the research design and methods should be well-defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. Describe the anticipated outcomes (short-term gains) from the proposed research and how they will be used as a foundation for future research projects. Explain the anticipated long-term gains from the proposed research project, including how the new understanding may ultimately contribute to the goal of advancing MS research, patient care, and/or quality of life.

- For the **"Correlates of Disease Activity and Progression in MS"** Focus Area, applications ***must*** demonstrate access to the relevant specimens and/or data of the proposed cohort. Refer to Attachment 10: Letter(s) Confirming Access to Specimens and/or Data for more details.

- ***For projects involving animal models of MS:*** Applicants should be prudent in the choice of animal model(s) for their proposed research project. Applicants must justify the relevance of their proposed animal model(s) to the specific aspect of human MS to be studied. Attachment 9: Animal Research Plan is required.

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

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

Clinical trials are not allowed under this Funding Opportunity. 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 FY24 MSRP EIRA program announcement will be grants (31 USC 6304).

The anticipated total costs budgeted for the entire period of performance for an FY24 MSRP EIRA] Award should not exceed **$320,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $1.6M to fund approximately five EIRA 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

The PI must:

- Possess a doctoral degree (or equivalent) from an accredited organization, and
- Have 4 years or less of postdoctoral research experience **at the time of application submission** (excluding clinical residency, clinical fellowship training, or extended medical leave).
- **Commit at least 50% of the effort toward the proposed MS research project.**
- **Can receive only one EIRA.**

Only postdoctoral fellows are eligible for this award. Faculty members and all other non-postdoctoral positions are not eligible to apply.

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

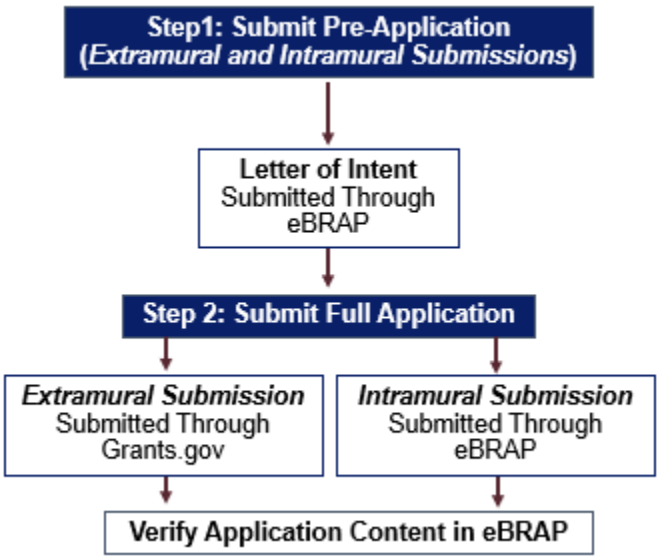
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural versus intramural), certain aspects of 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 HT942524MSRPEIRA 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 HT942524MSRPEIRA 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 the 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 MSRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-

application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is ***not*** required.
    - **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals who will provide letters of recommendation. The three letters of recommendation must include one from the primary Mentor and two from the secondary Mentor(s) (if applicable) or independent researchers who have had interaction with the PI. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

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

  Describe the proposed project in detail using the outline below. ***The Project Narrative is expected to be written by the PI while also showing evidence of appropriate direction from the Mentor(s).***

  - **Principal Investigator:** The application should describe the PI's career goals, demonstrating a strong personal commitment to pursuing an independent career as a leader at the forefront of MS research. Describe how the proposed research project and mentoring experience will promote the PI's development toward becoming an independent MS researcher.

  - **Mentor(s):** Describe each Mentor's background and experience in MS research. Explain how they will assist the PI throughout the period of performance in developing independence in MS research. Provide details on the amount and types of interactions between the Mentor(s) and the PI. Describe the track record of the Mentor(s) for mentoring early-stage investigators in MS research.

  - **Research Project:** Describe the proposed research project, including the background, hypothesis/objective, specific aims, experimental design, methods, and analyses. The application must provide a sound scientific rationale for the proposed project and its feasibility as established through a critical review and analysis of published literature and/or logical reasoning. Preliminary data are not required but may be included to support the scientific rationale and feasibility of the study. Address potential problem areas and present alternative methods and approaches. Include a statistical analysis plan for the proposed research, if applicable.

- **Focus Areas:** Briefly describe how the proposed research is relevant to one or more of the FY24 MSRP EIRA Focus Areas.

  - ***In addition, for research addressing the "Correlates of Disease Activity and Progression in MS" Focus Area:***

    - ***The study must leverage pre-existing specimens and/or data that are available at the time of application submission. Ongoing specimens and/or data collection from participants in the pre-existing cohort is allowed. However, collection of new set of specimens and/or data or recruitment of subjects is not permitted. Attachment 10: Letter(s) Confirming Access to Specimens and/or Data is required.***

    - Describe the proposed pre-existing cohort, including the type of specimens and/or data available.

    - Describe the size of the pre-existing cohort, including the intervention and control groups, and the expected statistical power of the study.

    - Explain how the cohort is appropriate for the study objective.

    - State when subject accrual and data/sample acquisition ended for the cohort.

    - If applicable, describe any additional specimens and/or data to be collected from participants in the pre-existing cohort at one additional time point and the value these specimens and/or data will add to the research.

    - If applicable, outline the recruitment process for previous participants in the cohort. Estimate the likely rates of recruitment, enrollment, and completion, and the expected statistical power of the results obtained from these additional data.

    - Outline plans and opportunities for eventual validation and independent replication of results in follow-up studies.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

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

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

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

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to the CDMRP Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Use of DOD Resources *(if applicable)*:** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

- **Use of U.S. Department of Veterans Affairs (VA) Resources *(if applicable)*:** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **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:** State the FY24 MSRP EIRA Focus Area(s) to be addressed. ***Describe how the proposed research project directly addresses one or more of the FY24 EIRA Focus Areas.*** Present the ideas and reasoning behind the proposed research project.

  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the hypothesis/objective.

  - **Specific Aims:** State the specific aims of the proposed research project.

  - **Study Design:** Describe the study design including appropriate controls.

- **Impact:** Explain how the proposed research project will produce results that are likely to translate, whether in the short or long term, to advancing MS research, patient care, and/or quality of life.

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

  Lay abstracts should address the points outlined below. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  - Describe the objectives and rationale for the proposed research project in a manner that ***will be readily understood by readers without a scientific or medical background.***

  - State the FY24 MSRP EIRA Focus Area(s) the proposed project addresses. ***Describe how the proposed research project directly addresses one or more of the FY24 MSRP EIRA Focus Area(s).***

  - Describe the applicability of the research to advance MS patient care:

    - What types of patients could it potentially help and how?

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

    - What is the projected time it may take to achieve a patient-related outcome?

  - If the research is too basic for short-term clinical applicability, describe how the outcomes of the proposed project will advance the field of MS research.

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the FY24 MSRP EIRA, refer to the "Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit the SOW as a PDF file.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".**

  Explain why the proposed research project is important and what impact it will have on one or more of the FY24 MSRP EIRA Focus Areas. Describe the potential impact(s) under two separate headings:

- ***Short-term impact:*** Detail the anticipated outcome(s) that will be directly attributed to the results of the proposed research project related to one or more of the FY24 MSRP EIRA Focus Areas.

- ***Long-term impact:*** Explain the anticipated long-term gains from the proposed research project, including how the new understanding will ultimately contribute toward the goal of advancing MS research, patient care, and/or quality of life related to one or more of the FY24 MSRP EIRA Focus Areas.

- **Attachment 7: Researcher Development Plan (one-page limit): Upload as "ResearchDev.pdf".**

  - Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed research project.

  - Indicate how the individualized Researcher Development Plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of MS, and effectively prepare them for a career as an independent MS researcher.

  - Describe how the Researcher Development Plan is supported by the environment and mentorship, including a description of ongoing MS research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI's primary institution (if applicable). If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a secondary Mentor at the collaborating institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the MS field. ***Do not reference or include members of the FY24 MSRP Programmatic Panel.***

- **Attachment 8: Eligibility Statement (one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official, to verify that the eligibility requirements have been met by the application submission deadline. The letter should provide the date (month/year) the PI completed/will complete requirements for their doctoral degree, and the date (month/year) the PI began/will begin postdoctoral research in the proposed setting.

- **Attachment 9: Animal Research Plan (three-page limit) (required if proposed research project involves animals): Upload as "AnimalPlan.pdf".** If the proposed research project involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
- Explain why the proposed model(s) is superior to other available animal models for the proposed research strategy.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

○ **Attachment 10: Letter(s) Confirming Access to Specimens and/or Data, if applicable: Upload as "Access.pdf".** If the application addresses the Focus Area of "Correlates of Disease Activity and Progression in MS," or if the application addresses more than one Focus Areas and one of them is "Correlates of Disease Activity and Progression in MS," provide a confirmation letter signed by the appropriate Institution Official who has the authority to confirm access to the proposed cohort specimens and/or data necessary to carry out the study. The study must leverage pre-existing specimens and/or data that are available at the time of application submission; ongoing specimens and/or data collection from participants in DOD FY24 Multiple Sclerosis Early Investigator Research Award 23 the pre-existing cohort are allowed. However, the recruitment of new subjects is not permitted.

○ **Attachment 11: 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 5, Section B, Representations.

○ **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should

be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c); and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d); and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
- **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 12.

Additional Application Components

In addition to the complete application package, FY24 MSRP EIRA applications also require the following components:

Three Confidential Letters of Recommendations

- One letter from the primary Mentor
- Two letters from the secondary Mentor(s) (if applicable) or independent researchers who have had interaction with the PI

The letters of recommendation should be prepared on letterhead, signed, and uploaded as PDF files to eBRAP by the Confidential Letters of Recommendation Submission Deadline. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application. The PI will not be able to view the letters.

- ***The confidential letter of recommendation from the Mentor*** should include a description of the Mentor's commitment to the PI's career development, mentorship in MS research, and ability to supervise the PI's research project. Mentor letters should also address the following (two pages per letter recommended):
    - The PI's potential for a highly productive career as an independent MS researcher.
    - Details of the proposed interactions of the Mentor with the PI during the PI's research project.
    - The mentoring environment, including ongoing MS research in the Mentor's laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a MS researcher.
    - The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application, if funded.
- ***Additional confidential letter(s) of recommendation:*** The remaining letter(s) (two pages per letter recommended) should describe the PI's unique qualifications and accomplishments that highlight their potential for success in pursuing a career in MS research. Specifically, each letter should offer the writer's perspective on:
    - The PI's qualifications, characteristics, and achievements.
    - The PI's potential for productivity and desire for establishing a successful and independent career in MS research.
    - The relevance of the proposed research project to developing the PI's career in MS research.

- The suitability of the Mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in MS research.

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

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

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

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

II.D.4. Submission Dates and Times

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

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

The maximum period of performance is **2** years. The period of performance is not to exceed **4** years.

The application's total costs budgeted for the entire period of performance should not exceed **$320,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 MSRP EIRA.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Clinical trial costs
- Equipment
- Mentor salary.

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:

- **Principal Investigator**
    - How the PI's achievements (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for a successful career as an MS researcher.
    - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in MS research.
    - To what extent the letters of recommendation from the Mentor(s) and others support the PI's potential for a highly productive career as a MS researcher.
    - Whether the PI's proposed level of effort is appropriate for successful completion of the proposed work.

- **Mentor(s)**
    - Whether there is at least one Mentor who is an established MS researcher, as evidenced by a demonstrated record of active funding and recent publications in MS research.
    - How the Mentor's (and secondary Mentor's, if applicable) own experience in MS and their research program and committed resources, support the ability to supervise the PI's research project.
    - To what extent the track record(s) of the Mentor(s) in previously mentoring early-stage investigators indicates the potential for successful mentoring of the PI in MS research.
    - Whether the Mentor letter(s) indicate(s) a high level of commitment to the PI's development as an MS researcher.
    - Whether the quality of the application suggests that the Mentor(s) provided appropriate guidance in its preparation.
- **Research Project**
    - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, MS-relevant preliminary data (if included), and/or logical reasoning.
    - Whether the experimental design and the statistical plan, if applicable, are appropriate for the research proposed.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
    - How well the application acknowledges potential problems and addresses alternative approaches.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
    - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
    - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
    - ***In addition, for research addressing the "Correlates of Disease Activity and Progression in MS" Focus Area, the following criteria also apply:***
        - How well the application demonstrates access to the proposed pre-existing cohort specimens and/or data.
        - To what extent the proposed pre-existing cohort is appropriate for the objective of the study.

  - To what extent the proposed pre-existing cohort is well-characterized and adequately controlled.
  - To what extent the statistical power of the study is appropriate, given the size of the cohort.
  - Whether subject accrual and sample/data acquisition for the preexisting cohort was complete at the time of submission.
  - If applicable, to what extent the plan to recruit previous participants in the cohort for follow-up studies is adequate.

- **Researcher Development Plan and Environment**
  - How well the application has outlined an individualized plan that will enable the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
  - How well the individualized Researcher Development Plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in MS research, and effectively prepare the PI for a career as an independent MS researcher.
  - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including professional interaction with established MS researchers.
  - To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements and/or intellectual property plans as applicable).

- **Impact**
  - To what extent the anticipated short-term outcomes will be directly attributed to the results of the proposed research project related to one or more of the FY24 MSRP EIRA Focus Areas.
  - To what extent the anticipated long-term gains from the proposed research project, including how the new understanding will ultimately contribute to the goal of advancing MS research, patient care, and/or quality of life, is related to one or more of the FY24 MSRP EIRA Focus Areas.

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.

- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

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

II.E.2. Application Review and Selection Process

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

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

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the MSRP 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 the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local 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 (RPPR).

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

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

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

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Letter of Intent was not submitted.
- Project Narrative is missing.
- Project Narrative exceeds page limit.
- Researcher Development Plan (Attachment 7) is missing.
- For studies utilizing animal models, Attachment 9: Animal Research Plan is missing.
- For studies addressing the "Correlates of Disease Activity and Progression in MS" Focus Area, Attachment 10: Letter(s) Confirming Access to Specimens and/or Data is missing.
- Application addresses developmental myelination, dysmyelination, blood-brain barrier permeability, basic mechanisms of demyelination, or peripheral immunomodulatory therapeutic strategies that limit tissue injury secondarily.
- Budget is missing.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 MSRP 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 MSRP Programmatic Panel members can be found at https://cdmrp.health.mil/msrp/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.
- For the "Central Nervous System Repair, Protection, and Regenerative Potential in MS" Focus Area, the application is for a study addressing developmental myelination, dysmyelination, basic mechanisms of demyelination, or peripheral immunomodulatory therapeutic strategies that limit tissue injury secondarily.
- For the "Biology and Measurement of MS Symptoms" Focus Area, the application is for a study of disease-modifying therapies that secondarily impact MS symptoms.
- For the "Correlates of Disease Activity and Progression in MS" Focus Area, the application does not demonstrate access to the relevant specimens and/or data of the proposed cohort (in Attachment 10: Letter(s) Confirming Access to Specimens and/or Data).
- The invited application proposes a different research project than that described in the pre-application.

- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application does not address one or more of the FY24 MSRP EIRA Focus Areas.
- Application includes classified research data and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns.

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.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Researcher Development Plan – Attachment 7, upload as "ResearchDev.pdf"	☐
Eligibility Statement – Attachment 8, upload as "Eligibility.pdf"	☐
Animal Research Plan – Attachment 9, upload as "AnimalPlan.pdf" *(if applicable)*	☐
Letter(s) Confirming Access to Specimens and/or Data – Attachment 10, upload as "Access.pdf" *(if applicable)*	☐
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form – Attachment 12, upload as "IGBudget.pdf" *(if applicable)*	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐
Additional Application Components	
Confidential Letters of Recommendation	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EIRA	Early Investigator Research Award
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
MSRP	Multiple Sclerosis Research Program
PDF	Portable Document Format
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
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