

# **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: W81XWH-21-MSRP-EIRA**

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical  
Research and Development**

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

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 7, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, October 1, 2021
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, October 6, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, October 6, 2021
- **Peer Review:** December 2021
- **Programmatic Review:** February 2022

*This program announcement must be read in conjunction with the General Application Instructions, version 604. The General Application Instructions document is available for downloading from the [Grants.gov](https://www.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

Applications to the Fiscal Year 2021 (FY21) Multiple Sclerosis Research Program (MSRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The MSRP was initiated in 2009 to provide support for *pioneering concepts and high-impact research* that are relevant to the prevention, etiology, pathogenesis, assessment, and treatment of multiple sclerosis (MS) to ultimately lessen its personal and societal impact. Appropriations for the MSRP from FY09 through FY20 totaled \$73.1 million (M). The FY21 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. FY21 MSRP EIRA Focus Areas

All applications submitted to the FY21 MSRP Early Investigator Research Award (EIRA) program announcement *must* address one or more of the following Focus Areas:

- **Central Nervous System Regenerative Potential in Demyelinating Conditions**

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
- Epigenetic control
- Cell-based therapies
- Identification of factors that promote repair
- Innate immune-mediated mechanisms within the central nervous system
- Development of biomarkers of repair

***Utilization and/or development of models that reflect the disease progression and translational approaches to evaluate benefit are encouraged.***

**Note:** Studies addressing developmental myelination, dysmyelination, blood-brain barrier permeability, basic mechanisms of demyelination, or peripheral inflammatory mechanisms and anti-inflammatory 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 modification 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; collection of a single set of specimens and/or data collected at one additional time point from participants in the pre-existing cohort is allowed.

***Applications proposing to use specimens and/or data that are still under collection at the time of submission will not be considered for funding.***

- **Biology and Measurement of MS Symptoms**

Supports studies of MS symptoms, which may include pain, fatigue, depression, anxiety, loss of bladder control, 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 modification therapies), controls, and/or verification of symptoms.

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

- **Factors Contributing to MS Etiology, Prodrome, Onset, and Disease Course**

Supports studies to identify the role of various factors in MS etiology, prodrome, onset, activity, and progression. Examples of factors include but are not limited to genetics, epigenetics, environment, infection, sex, ethnicity, age, comorbidities, health behaviors, socioeconomics, access to care, etc.

- **Interactions between MS and COVID-19**

Supports studies of the interaction between MS and COVID-19. Examples of acceptable studies include but are not limited to the following:

- Effects of MS and disease-modifying medications used to treat MS on susceptibility to COVID-19, manifestations or severity of infection, or protective immunity following infection
- Management of COVID-19 in people with MS
- Effects of COVID-19 on MS pathogenesis or disease behavior and mechanisms, including both patients and animal models
- Safety and efficacy of SARS-CoV-2 vaccination in people with MS, including effects of disease-modifying therapies on protective immunity following vaccination
- Effects of pandemic-related health behaviors on MS management
- Long-term manifestations of COVID-19 in people with MS including but not limited to fatigue and cognition

## **II.A.2. Award History**

The MSRP Early Investigator Research Award mechanism is being offered for the first time in FY21.

## **II.B. Award Information**

The Early Investigator Research Award 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 Early Investigator Research Award are expected to be written by the 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 Principal Investigator (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 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 and/or patient care.
- 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.
- **Note 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.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY21 MSRP EIRA will not exceed **\$200,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

***The CDMRP expects to allot approximately \$1.9M to fund approximately six EIRA Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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 FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.***

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is **not** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

***Clinical trials are not allowed under this funding opportunity.*** A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**Clinical research is defined** as: (1) patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) epidemiologic and behavioral studies; and (3) outcomes research and health services research. **Note:** Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided at eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>).

**Research Involving Animals:** All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. **Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.** Refer to the General Application Instructions, Appendix 1, for additional information.

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

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

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

**Government Agencies Within the United States:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

**Intramural DOD Organization:** A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

**USAMRAA makes awards to eligible organizations, not to individuals.**



### **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 or clinical fellowship training); and
- **Commit at least 50% of the effort toward the proposed MS research project.**

**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.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

### **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 in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

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

## **II.D. Application and Submission Information**

***Submission of applications that are essentially identical or 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).***

#### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

### ***Intramural DOD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org).

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

### **II.D.1. Address to Request Application Package**

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1, Full Application Guidelines](#)).

***The application title, eBRAP log number, 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 CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application submission deadline.

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

***During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.***

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

The applicant organization and associated PI and Mentor(s) identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY21 MSRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications,

refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

**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 the letter.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

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

*The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

### **II.D.2.b.i. Full Application Guidelines**

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's

computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

***Do not password protect any files of the application package, including the Project Narrative.***

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DOD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-21-MSRP-EIRA from Grants.gov ( <a href="https://www.grants.gov">https://www.grants.gov</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-MSRP-EIRA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).
<b>Full Application Package Components</b>	
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a></li> <li>• <a href="#">Additional Application Component(s)</a></li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> <li>• <a href="#">Other</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DOD Submissions
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <b>prior to</b> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><u><a href="#">Application Verification Period</a></u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>

Extramural Submissions	Intramural DOD Submissions
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

**SF424 Research & Related Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

**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 4.*

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **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 that provide additional information to expand 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 become 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 toward 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 FY21 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. Collection of a single set of specimens and/or data collected at one additional time point from participants in the existing cohort is allowed.***
    - ❖ 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. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **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 or not 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 or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- **Transcripts:** Include a copy of the *PI’s* transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the “Full Announcement” page in Grants.gov) in place of the transcript.
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (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.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. 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.
- **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. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Applicants should note that programmatic reviewers may not have access to the full application and therefore rely on the technical abstract for appropriate description of the

project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

Technical abstracts should be written using the headings below:

- **Background:** State the FY21 MSRP EIRA Focus Area(s) to be addressed. **Describe how the proposed research project directly addresses the Focus Area(s).** 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 and/or patient care.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. **Do not include proprietary or confidential information.** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. **Do not duplicate the technical abstract:**

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 FY21 MSRP EIRA Focus Area(s) the proposed project addresses. **Describe how the proposed research project directly addresses one or more of the FY21 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”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Early Investigator Research Award, refer to “*Suggested SOW Strategy Generic Research*” and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

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

Explain why the proposed research project is important and the impact it will have on one or more of the FY21 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 FY21 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 to the goal of advancing MS research and/or patient care related to one or more of the FY21 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 [FY21 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 (required if the application addresses the “Correlates of Disease Activity and Progression in MS” Focus Area): Upload as “Access.pdf”.** If the application addresses the “Correlates of Disease Activity and Progression in MS” Focus Area, provide a letter of support 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; Collection of a single set of specimens and/or data collected at

one additional time point from participants in the pre-existing cohort is allowed.  
*Applications proposing to use specimens and/or data that are still under collection at the time of submission will not be considered for funding.*

- **Attachment 11: Representations, if applicable (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 Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

**Research & Related Personal Data:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

**Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch\_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
  - Include Mentor’s (and secondary Mentor’s, if applicable) biographical sketch.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - Include Mentor’s (and secondary Mentor’s, if applicable) previous/current/pending support.

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

**Budget Justification (no page limit): Upload as “BudgetJustification.pdf”.** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

**Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 12](#). (Refer to the General Application Instructions, Section IV.A.4, for

detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

### **Additional Application Components**

In addition to the complete application package, Early Investigator Research Award applications also require the following components:

- **Three Confidential Letters of Recommendations**

The letters of recommendation should be provided 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) 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 (two pages per letter recommended):
  - 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.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

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

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

### **Applicant Verification of Full Application Submission in eBRAP**

***For Both Extramural and Intramural Applicants:*** eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

***Extramural Submission:*** The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

***Intramural DOD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

***For All Submissions:*** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

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

The maximum period of performance is **2** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$200,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$200,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total 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:

- Travel in support of collaborations
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meeting is to present project information or disseminate project results from the MSRP Early Investigator Research Award.

Must not be requested for:

- Clinical trial costs
- Equipment
- Mentor salary

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

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

Refer to the General Application Instructions, Appendix 4, 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 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.
- ***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 [FY21 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 and/or patient care related to one or more of the [FY21 MSRP EIRA Focus Areas](#).

In addition, the following **unscored** criteria will also contribute to the overall evaluation of the application:

- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - 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 mission of the Defense Health Program and FY21 MSRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact

### **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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the MSRP will be provided to the PI and posted on the CDMRP website.

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 panel. Violations of confidentiality can result in the dissolving 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 another 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 200.88, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.E.4. Anticipated Announcement and Federal Award Dates**

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

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

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

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs:** An institution of higher education, hospital, or other non-profit 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. Refer to the General Application Instructions, Section III.A.5.

***Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds.*** 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.**

**Federal Government Organizations:** Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

### **II.F.1.a. PI Changes and Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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 2, Section B, for general information on organization or PI changes.

### **II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

### **II.F.3. Reporting**

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***



Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if 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 if 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 will incorporate 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 \$10,000,000 are required to provide information to FAPIIS 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. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

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

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

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

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

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

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

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

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by 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 604a. The program announcement numeric version code will match the General Application Instructions version code 604.

### **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 pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Researcher Development Plan ([Attachment 7](#)) is missing.
- Studies utilizing animal models but [Attachment 9](#) 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 inflammatory mechanisms and anti-inflammatory therapeutic strategies that limit tissue injury secondarily.
- Project Narrative is missing.
- 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

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

The following may result in administrative withdrawal of the pre-application or application:

- An FY21 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. *A list of the FY21 MSRP Programmatic Panel members can be found at <https://cdmrp.army.mil/msrp/panels/panels21>.*
- 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.
- 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 FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.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.
- For the Central Nervous System Regenerative Potential in Demyelinating Conditions Focus Area, the application is for a study addressing developmental myelination, dysmyelination, blood-brain barrier permeability, basic mechanisms of demyelination, or peripheral inflammatory mechanisms and anti-inflammatory therapeutic strategies that limit tissue injury secondarily

- The application proposes to use specimens and/or data that are still under collection at the time of submission.
- For the Biology and Measurement of MS Symptoms Focus Area, the application is for a study of disease-modifying or regenerative 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](#)).
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 pre-application or application does not address one or more of the [FY21 MSRP EIRA Focus Areas](#).

#### **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. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> )	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Researcher Development Plan: Upload as Attachment 7 with the file name "ResearchDev.pdf"	
	Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf"	
	Animal Research Plan: Upload as Attachment 9 with file name "AnimalPlan.pdf" if applicable	
	Letter(s) Confirming Access to Specimens and/or Data: Upload as Attachment 10 with file name "Access.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

<b>Application Components</b>	<b>Action</b>	<b>Completed</b>
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget ( <b>extramural submissions only</b> )	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget ( <b>intramural submissions only</b> )	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	
<b>Additional Application Components</b>	<b>Action</b>	<b>Completed</b>
Confidential Letters of Recommendation	Confirm upload to eBRAP	

## APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EIRA	Early Investigator Research Award
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
K	Thousand
M	Million
MIPR	Military Interdepartmental Purchase Request
MS	Multiple Sclerosis
MSRP	Multiple Sclerosis Research Program
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
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