

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Melanoma Research Program

Mid-Career Accelerator Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-MRP-MCAA

**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), August 4, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, August 26, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, August 31, 2021
- **Peer Review:** October 2021
- **Programmatic Review:** January 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 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) Melanoma Research Program (MRP) 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). The MRP was initiated in 2019 to provide support for research of exceptional scientific merit in the field of melanoma. Appropriations for the MRP from FY19 through FY20 totaled \$30 million (M). The FY21 appropriation is \$30M.

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

The vision of the MRP is to prevent melanoma initiation and progression.

The mission of the MRP is to promote earlier interventions to enhance mission readiness and to diminish melanoma burden on Service Members, Veterans, and the American public.

II.A.1. FY21 MRP Challenge Statement and Focus Areas

All applications must address the FY21 MRP Challenge Statement.

FY21 MRP Challenge Statement: The Melanoma Research Program (MRP) challenges the research community to redefine the concept of prevention. The clinical, research, and patient communities traditionally view prevention as the use of sunscreen/blockers to protect melanocytes from harmful ultraviolet (UV) radiation. While recognizing the usefulness of current primary prevention strategies (e.g., sunscreens and UV avoidance), the MRP tasks the research community to redefine prevention to include the entire melanomagenesis process and for all variants of melanoma. In recognizing that melanomagenesis is a multistep process, a new paradigm of prevention may include detection, monitoring, and impeding the initiation and progression of primary melanoma, blocking emergence from tumor dormancy and development of micro-metastases. Each step along the disease process from initiation to metastasis is an opportunity to detect, monitor, or for innovative therapeutic modalities to stop disease progression. The MRP challenges the research community to prevent melanoma earlier in the disease cycle thus preventing metastasis. The MRP looks to shift the paradigm of prevention of all types of melanoma by investing in research studies focused on eliminating the development and progression of cutaneous or a rare melanoma subtype. For more information on the MRP Challenge Statement, review https://cdmrp.army.mil/mrp/pdfs/Challenge_statement2021.pdf.

With the exception of those studies investigating rare melanomas, the FY21 MRP is not requesting research into established macrometastatic disease, models of metastatic disease using established cell lines, or treatment of macrometastatic disease. The MRP encourages

studies for rare melanomas across the entire spectrum from initiation to distant macro-metastasis.

The MRP strongly encourages the use of Department of Defense (DOD)/Department of Veterans Affairs (VA) databases and participation by DOD/VA investigators.

FY21 MRP Focus Areas: The FY21 MRP Focus Areas promote the role of prevention throughout the disease process. Applicants are encouraged to review the FY21 MRP Landscape: <https://cdmrp.army.mil/mrp/pdfs/Melanoma%20Research%20Program%20Landscape%20Document.pdf>.

To be considered for funding, applications for the MRP FY21 Mid-Career Accelerator Award (MCAA) *must* address at least one of the following FY21 MRP Focus Areas:

- Identify methods to decrease risk of melanoma development beyond sunscreen and protective clothing.
- Identify and understand risk factor determinants for melanoma, including variants (e.g., uveal, acral, mucosal melanoma).
- Identify how the tumor microenvironment (e.g., stromal, immune, microbiome) impact tumor initiation, response to therapy, progression, and dormancy.
- Understand how precursor lesions and endogenous host factors may lead to melanomagenesis.
- Develop new decision-making tools for the detection and diagnosis of melanoma that includes easily accessible technology (beyond the dermoscope) for primary care physicians and dermatologists.
- Develop prediction and surveillance tools for distinguishing patient at risk for recurrence and/or metastasis. Identify biological determinants to differentiate patient populations
- Understand mechanisms that underlie metastatic spread to different (regional/nodal) sites or the different distant sites of metastasis from acral, mucosal, and uveal melanomas.
- Delineate the molecular pathways, tumor microenvironment, immune response that influence metastatic spread, recurrence, and/or dormancy.

II.B. Award Information

The MRP MCAA supports independent, mid-career investigators to conduct impactful research in the field of melanoma. The MCAA presents an opportunity for mid-career investigators to obtain funding to perform impactful research that will accelerate their career to become leaders in the melanoma research community. ***Preliminary data relevant to melanoma are required.*** Logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.

Key elements of the MCAA mechanism are as follows:

- **Principal Investigator (PI):** The PI must be an independent, mid-career researcher, or physician-scientist at the level of Assistant or Associate Professor or equivalent. The PI must be *at least 7 years or more* from their first faculty-level appointment. ***Instructors and full professors are not eligible.*** The PI must demonstrate receipt of at least one previously peer-reviewed extramural funding. The PI's record of accomplishments (publications, presentations, patents, etc.) and the proposed research will be evaluated regarding the PI's potential for contributing to the FY21 MRP Focus Area(s) in [Section II.A.1](#).
- **Impact:** The application must articulate the potential impact the proposed work will have on melanoma research and/or patient care. Impactful research will, if successful, accelerate the movement of promising ideas in melanoma research into clinical applications. The impact of the proposed research must relate to at least one of the FY21 MRP Focus Areas in [Section II.A.1](#) and be responsive to the FY21 MRP Challenge Statement. The relevance of all research, including basic, should relate to the outcomes and how they may benefit those affected by melanoma.
- **Continuity Development Plan:** The continuity development plan should include a clearly articulated strategy for furthering the career of the PI including. The goal of the MCAA is to support candidates who have the potential to become leaders in the melanoma field. The Continuity Development Plan ([Attachment 6](#)) should demonstrate the candidate's dedication and potential in the field of melanoma.
- **MRP Focus Areas:** The proposed research must address at least one of the FY21 MRP Focus Areas in [Section II.A.1](#) and show how the proposed research addresses the FY21 MRP Challenge Statement.

Studies involving non-melanoma skin cancers are not allowed under the FY21 MRP.

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 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.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the

lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations, provided they are within the limitations of this funding opportunity and fit within the FY21 MRP priorities.

The anticipated direct costs budgeted for the entire period of performance for an FY21 MRP MCAA will not exceed **\$750,000**. 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 \$4.8M to fund approximately four MCAA 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 U.S. Army Medical Research and Development Command (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 Research Protections Office Resources and Overview 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.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trials are not allowed.

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.

Use of DOD or VA Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

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

- To be named as the PI on the application, the investigator must be at the level of Assistant or Associate Professor (or equivalent).
- Instructors and Full Professors are not eligible.
- **Must** be at least 7 years or more from their first faculty-level appointment at the time of application submission.
- **Must** be able to demonstrate receipt of at least one peer-reviewed extramural funding award.
- An investigator may be named on only one MCAA application as a PI.

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.
- 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.
- Full application packages must be accessed and submitted at 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 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 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/>).

The applicant organization and associated PI 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 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 applicants 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 MRP 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 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. Include the FY21 MRP Focus Area(s) (listed in [Section II.A.1](#)) under which the application will be submitted. 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.

- **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 |
|--|--|
| Application Package Location | |
| <p>Download application package components for W81XWH-21-MRP-MCAA from Grants.gov (https://www.grants.gov) 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.</p> | <p>Download application package components for W81XWH-21-MRP-MCAA from eBRAP (https://ebrap.org).</p> |
| Full Application Package Components | |
| <p>SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.</p> | <p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: 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"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form | <p>Tab 3 – Full Application Files: 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"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: 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 |
|---|---|
| Application Package Submission | |
| <p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. 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 at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><i>Note:</i> 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 <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p> | <p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: 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. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p> |
| <u>Application Verification Period</u> | |
| <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 <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></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 <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> 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 |
|---|---|
| Further Information | |
| <p>Tracking a Grants.gov Workspace Package. 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 (10-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. ***Inclusion of preliminary data relevant to melanoma is required.***
 - **Background:** Describe the critical scientific or clinical issue that, if successfully addressed, will have a major impact on at least one of the FY21 MRP Focus Areas in [Section II.A.1](#). Delineate important discoveries, outcomes, or advancements that can be attributed to the PI’s work in melanoma.
 - **Hypothesis and Objective:** State the hypothesis to be tested and the objective to be reached regarding a critical scientific or clinical issue relevant to at least one of the FY21 MRP Focus Areas in [Section II.A.1](#). State how the research addresses the FY21 MRP Challenge Statement.
 - **Specific Aims:** State the specific aims of the study.
 - **Research Strategy and Feasibility:** Describe the rationale, experimental design, and methodology appropriate to test the hypothesis and reach the final objective. Include preliminary data and reconcile it with objectives of the research proposed. Demonstrate how the research is based on strong melanoma relevant preliminary data and/or previous clinical and/or translational research outcomes. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI or collaborators named on this application must be included. Describe the statistical plan with appropriate power analysis and how it supports the sample size. Describe whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed. Describe potential problems and pitfalls, and address alternative approaches. Demonstrate the availability of tissue, data, or human subjects, if applicable. Research projects may include preclinical studies in animal models or clinical research involving human subjects and human anatomical substances. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. Describe all animal studies and how the studies are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable. ***This award may not be used to fund or conduct clinical trials, but correlative studies are permitted.***
 - Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. If women and minorities are excluded, provide a rational justification for the exclusion.
- **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.

- **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.
- **Inclusion Plan (only required for applications proposing accrual of human subjects):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **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 VA Resources (if applicable):** Provide a letter of support from 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. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution 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. *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.

- **Personnel:** Describe the PI’s background in the field of melanoma, addressing important discoveries, outcomes, or advancements attributed to the PI’s work. Describe the PI’s potential for a career at the forefront of melanoma research.
- **Background:** Present the ideas and reasoning behind the proposed work. Describe the previous laboratory, clinical and/or translational research outcomes upon which the study is founded.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design and methodology.
- **Impact:** Briefly describe how the proposed project will have impact on at least one of the FY21 MRP Focus Areas in [Section II.A.1](#). Describe the impact of the research on the FY21 MRP Challenge Statement.
- **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. Do not duplicate the technical abstract.*** 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. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

- Describe the PI’s potential as a leader in melanoma research.
- State the FY21 MRP Focus Area(s) in [Section II.A.1](#) to be addressed by the research project. State how the study addresses the FY21 MRP Challenge Statement.
- Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.***
- In laypersons’ terms, describe the ultimate applicability of the research. What types of patients will it help, and how will it help them? What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field. What are the likely contributions of this study to advancing the field of cancer research and/or patient care? If the research is basic, describe the long-term goals that are related to patient care, outcomes, or survivorship. Basic research should have an ultimate goal of the betterment of the melanoma patient or family, etc.

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested Statement of Work (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 MCAA, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort, and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

- **Attachment 6: Continuity Development Plan: (two-page limit): Upload as “ConDP.pdf”.** Articulate the strategy for furthering the career of the PI including strategies to collaborate with leaders in the melanoma field, targeted career milestones (include plans to accomplish the milestones), approaches to expand PI’s knowledge base and put the gained knowledge into usable action in the field of melanoma, plans to obtain and build career viability through further funding with potential research outcomes. Include information that supports the PI has been previously funded by a peer reviewed extramural funding organization. Demonstrate that the PI has the potential to become a leader in the field of melanoma.
- **Attachment 7: Research Outcomes Plan: (one-page limit): Upload as “Outcomes.pdf”.** Describe the anticipated research outcomes including knowledge products, clinical products for development, etc. Describe the methods and strategies proposed to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project. Detail the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for). Demonstrate that a plan for management of intellectual property is in place.
- **Attachment 8: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Justify how the proposed research will have potential impact in terms of short or long term outcomes in the field melanoma research and/or patient care. Relate how the proposed research advances at least one of the FY21 MRP Focus Areas in [Section II.A.1](#) and is responsive to the FY21 MRP Challenge Statement. The relevance of all research, including basic, should relate to the outcomes and how they may benefit those affected by melanoma. *The Impact Statement should be written in plain language for laypersons.*
- **Attachment 9: Statement of Eligibility (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. The letter should verify that the PI is *at least 7 years or more* from their first faculty-level appointment. ([Refer to Section II.C, Eligibility Information.](#)) The letter should verify independent laboratory space and that the PI has been named on at least one peer reviewed extramural funding award.

- **Attachment 10: 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 11: 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”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

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. Budget justification should include level of effort by each team member. If a team member is not requesting salary, then the justification should delineate their level of effort.

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 11](#). (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.

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 **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **\$750,000** 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.

For this award mechanism, direct costs must be requested for:

- Costs for one investigator to travel to one meeting in the second year of the MCAA to a meeting of the FY21 MRP Melanoma Academy (place and time to be determined). The intent of this travel is to further the networking and collaborations of the MCAA investigator and therefore the travel costs are to present project information or disseminate project results from the FY21 MRP MCAA.

May be requested for (not all inclusive):

- Travel costs in support of multidisciplinary collaborations.
- Costs for one investigator to travel to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the MRP MCAA.

Must not be requested for:

- Clinical trial costs

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**
 - Whether the PI meets the eligibility requirements.
 - Based on the biographical sketch, whether the PI's background includes investigations within the field of melanoma.
 - Whether important discoveries, outcomes, or advancements can be attributed to the PI's work in melanoma.
 - Whether the PI has the potential for a career at the forefront of melanoma research.
 - Based on information from the biographical sketch, to what degree the background and experience of the PI is appropriate to accomplish the proposed research.
 - How appropriate the levels of effort based on the budget justification are for successful conduct of the proposed work
- **Research Strategy and Feasibility**
 - To what extent the rationale, experimental design, and methodology are appropriate to test the hypothesis and reach the final objective.
 - Whether the included preliminary data reconciles with the objectives of the research proposed.

- To what extent the statistical plan is appropriate, and whether the power analysis supports the sample size (i.e., whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed).
 - How well potential problems and/or pitfalls are identified, and whether alternative approaches are addressed.
 - Whether the applicant demonstrates the availability of tissue, data, or human subjects, if applicable.
 - Whether the application includes a plan for the recruitment of human subjects or the acquisition of samples and documents the experience of the PI and/or key collaborators in recruiting human subjects for similar projects, if applicable.
 - If applicable, to what extent the human subject population described is appropriate for the study and there is clear demonstration of access to the designated population.
 - 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, if applicable.
 - Whether the strategies for the inclusion of women and minorities are appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. If women and minorities are excluded, to what extent the application provided a rational justification.
- **Impact**
 - To what degree the application justifies how the proposed research will have potential impact in terms of short- or long-term outcomes in the field melanoma research and/or patient care.
 - Whether the proposed research advances at least one of the FY21 MRP Focus Areas in [Section II.A.1.](#)
 - Whether the proposed research is responsive to the FY21 MRP Challenge Statement in [Section II.A.1.](#)
- **Continuity Development Plan:**
 - Whether the application articulates a strategy for furthering the career of the PI in terms of collaborating with leaders in the melanoma field.
 - Whether the application includes targeted career milestones and whether the PI can accomplish the milestones.
 - To what extent approaches to expand the PI's knowledge base and put the gained knowledge into usable action in the field of melanoma will be successful.

- Whether plans to obtain and build career viability through further funding with potential research outcomes are included.
- Whether the application includes information demonstrating that the PI has been previously funded by a peer-reviewed extramural funding organization.

- **Research Outcomes Plan**

- Whether the application described the anticipated research outcomes, including knowledge products, clinical products for development, etc.
- How well the application demonstrated methods and strategies to move the anticipated research outcomes to the next phase of development or clinical application after successful completion of the project.
- Whether the application detailed the funding strategy to transition to the next level of investigation, development, and/or commercialization (e.g., partners, internal/external funding opportunities to be applied for).
- Whether a plan for management of intellectual property is in place.

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

- **Personnel**

- Whether the application demonstrates the PI has assembled a research team with the expertise and background to accomplish the proposed project.
- Based on the budget justification, whether the level of effort of each research team member is appropriate to accomplish the research.

- **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.

- **Environment**

- To what degree the scientific environment is appropriate for the proposed research.
- To what degree the research requirements are supported by the availability of, and accessibility to, facilities and resources (including collaborative arrangements).
- To what degree the quality and extent of institutional support are appropriate.

- **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 MRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Programmatic relevance the FY21 MRP Challenge Statement in [Section II.A.1](#)
 - Programmatic relevance to the FY21 MRP Focus Areas in [Section II.A.1](#)
 - Potential for the PI to be leader in the field of melanoma
 - 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 MRP 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.

Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*): Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

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 \$10M 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

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

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 applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- 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 Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY21 MRP 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 MRP Programmatic Panel members can be found at <https://cdmrp.army.mil/mrp/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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application does not address the FY21 MRP Challenge Statement in [Section II.A.1](#).
- The application does not address at least one of the FY21 MRP Focus Areas in [Section II.A.1](#).
- The PI is named on more than one MCAA application.

- The main subject of the research is non-melanoma skin cancers.

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 (extramural submissions only) | Complete form as instructed | |
| Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only) | 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" | |
| | Continuity Development Plan: Upload as Attachment 6 with file name "ConDP.pdf" | |
| | Research Outcomes Plan: Upload as Attachment 7 with file name "Outcomes.pdf" | |
| | Impact Statement: Upload as Attachment 8 with file name "Impact.pdf" | |
| | Statement of Eligibility: Upload as Attachment 9 with file name "Eligibility.pdf" | |
| | Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf" if applicable | |
| | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable | |
| Research & Related Personal Data | Complete form as instructed | |

| Application Components | Action | Completed |
|--|--|-----------|
| 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 (extramural submissions only) | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field | |
| Budget (intramural submissions only) | 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 | |

APPENDIX 1: ACRONYM LIST

| | |
|----------|---|
| ACOS/R&D | Associate Chief of Staff for Research and Development |
| ACURO | Animal Care and Use Review Office |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| DHA | Defense Health Agency |
| 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 |
| 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 |
| LOI | Letter of Intent |
| M | Million |
| MCAA | Mid-Career Accelerator Award |
| MIPR | Military Interdepartmental Purchase Request |
| MRP | Melanoma Research Program |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| 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 |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC | United States Code |
| UV | Ultraviolet |
| VA | Department of Veterans Affairs |