

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

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Melanoma Research Program**

**Focused Program Award – Rare Melanomas**

**Announcement Type: Initial**

**Funding Opportunity Number: HT9425-23-MRP-FPA-RM**

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

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

- **Pre-Application Submission (Letter of Intent) Deadline:** 5:00 p.m. Eastern time (ET), August 31, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, September 22, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, September 29, 2023
- **Peer Review:** November 2023
- **Programmatic Review:** January/February 2024

*This program announcement must be read in conjunction with the General Application Instructions, version 803. 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 2023 (FY23) 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 4001 (10 USC 4001). 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 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 FY22 totaled \$100 million (M). The FY23 appropriation is \$40M.

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

*The vision of the MRP is to prevent melanoma initiation and progression. The mission of the MRP is to support development of earlier interventions to enhance mission readiness and diminish melanoma burden on Service Members, Veterans, their families, and the American public.*

#### II.A.1. Award History

The MRP Focused Program Award – Rare Melanomas (FPA-RM) mechanism was first offered in FY22. The MRP received eight FPA-RM applications, and three were recommended for funding.

### II.B. Award Information

The FY23 MRP FPA-RM is intended to support a multidisciplinary research program of at least two, but not more than three, distinct but complementary projects addressing an overarching question relevant to rare melanomas (see Figure 1 on the next page). *Applications for FPA-RM may propose projects across the entire research spectrum (biology, etiology, prevention, diagnosis and detection, prognosis, treatment, and quality of life) and must address a critical unmet need relevant to rare melanomas (e.g., uveal, acral, mucosal, pediatric).*

*Studies involving non-melanoma skin cancers are not allowed under the FY23 MRP.*

#### **The key aspects of this award are:**

**Overarching Question:** FPA-RM applications must describe a unifying, overarching question that will be investigated by a set of research projects to address a critical unmet need relevant to rare melanoma research and/or patient care. The question may focus on one specific rare melanoma, or the question may be designed to address a critical unmet need that is relevant to multiple rare melanomas.

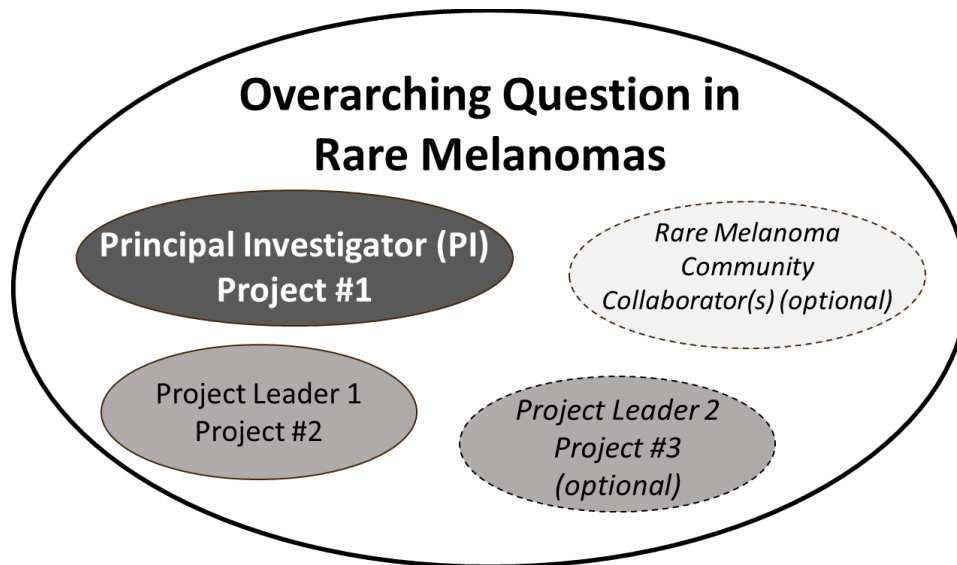


Figure 1. For the FY23 FPA-RM, a research team, consisting of a PI and one or two Project Leaders, will engage in at least two, but not more than three, distinct but complementary projects to answer an overarching question relevant to rare melanomas. The research team is encouraged to include rare melanoma community collaborators (e.g., patients, survivors, caregivers) to maximize the impact and translatability of the research for this community.

**Research Team:** The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large, focused projects. The PI is required to devote a minimum of 10% effort to this award. The PI will be the lead for one of the proposed research projects and is expected to create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team. The research team assembled by the PI should be highly qualified and multidisciplinary, with an identified Project Leader(s) for the complementary and synergistic research project(s). The resources and expertise brought to the team by the Project Leader(s) should combine to create a robust collaboration.

**Research Projects:** Applications should include multiple, distinct research projects that are each led by individual Project Leaders and address complementary aspects of the overarching question. Individual research projects may range from exploratory, hypothesis-developing studies through clinical trials. While individual projects should be capable of standing on their own high scientific merits, they should also be interrelated and synergistic to advance a solution beyond what would be possible through individual efforts. Each project, including hypothesis-developing studies, should propose a unique approach to addressing the overarching question and be capable of producing research findings with potential to impact the rare melanoma field and/or patient care. There should be a clear intent to progress toward translational/clinical work over the course of the effort. This award mechanism is not intended to support a series of research projects that are dependent on the success of the other project(s). **Clinical trials are allowed.** A research project proposing a clinical trial **must** include preliminary data. All other research projects must be based on a strong scientific rationale that supports the feasibility of the proposed approach(es).

**Implementation Plan:** The research strategy to address the overarching question should be supported by an implementation plan that identifies critical milestones and outlines the

knowledge, resources, and/or technical innovations that will be utilized to achieve the milestones. A plan for assessing individual project performance and progress toward addressing the overarching question should be included in the implementation plan. For multi-institutional collaborations, the application should discuss plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, and/or products obtained during the study will be handled. Participating organizations should formalize an intellectual and material property plan.

**Milestone Meeting:** The PI will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting to be held either virtually or in person in the National Capital Area after the conclusion of year 2 of the period of performance. The intent of the Milestone Meeting is to assess research progress, address problems, and define future directions. Research milestones to be accomplished by the end of year 2 must be clearly defined in the Statement of Work (SOW) and will be finalized during award negotiations. Up to two additional members of the research team may be invited to the meeting. If the research team includes rare melanoma patient community collaborators (see below), they should also be invited to attend the Milestone Meeting. The Milestone Meeting will be attended by members of the MRP Programmatic Panel, CDMRP staff, the USAMRAA Grants Officer, and other Department of Defense (DOD) stakeholders. Continued funding may be contingent upon the successful completion of specific research milestones and goals.

### **Other important considerations:**

**Rare Melanoma Community Collaborations:** Applicants to the FPA-RM are encouraged, but not required, to collaborate with the rare melanoma patient community (e.g., melanoma patients, survivors, caregivers) to maximize the impact and translatability of the research for this community. This collaboration can be approached in several ways. Examples of collaborative research approaches are listed below, but each research team may pursue other options as appropriate for the overarching question being explored:

- The research team includes at least one rare melanoma patient advocate who will provide advice and consultation throughout the planning *and* implementation of the research project.
- The research team establishes partnerships with at least one community-based organization that provides advice and consultation throughout the planning and implementation of the research project. Community-based organizations may include advocacy groups or other formal organizational stakeholders that can speak to the needs of the rare melanoma community.
- The research team assembles a rare melanoma community advisory board. The advisory board may include rare melanoma patient advocates, a coalition of community-based organizations, or any combination thereof that provides advice and consultation *throughout* the planning and implementation of the research project.

Additional information on collaborative research approaches and the MRP's focus on rare melanomas can be found in:

- Congressionally Directed Medical Research Programs. The Melanoma Research Program's Renewed Focus on Rare Melanomas and a New Funding Opportunity. [https://cdmrp.army.mil/mrp/research\\_highlights/22RenewedFocusRareMelanomas\\_highlight](https://cdmrp.army.mil/mrp/research_highlights/22RenewedFocusRareMelanomas_highlight).
- Spears PA. 2021. 2021. Patient engagement in cancer research from the patient's perspective. *Future Oncology* 17(28):3717-3728. doi: [10.2217/fon-2020-1198](https://doi.org/10.2217/fon-2020-1198). Epub 2021 Jul 2. PMID: [34213358](https://pubmed.ncbi.nlm.nih.gov/34213358/)
- Salamone JM, Lucas W, Brundage SB, et al. 2018. Promoting scientist-advocate collaborations in cancer research: Why and how. *Cancer Research* 78(20):5723-5728. doi:[10.1158/0008-5472.CAN-18-1600](https://doi.org/10.1158/0008-5472.CAN-18-1600).
- U.S. Food and Drug Administration (FDA). Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development. <https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development>.

**Relevance to Military Health:** The MRP seeks to support research that is relevant to the healthcare needs of military Service Members, Veterans, and their families. Applicants are strongly encouraged to consider the following examples of how a project may demonstrate relevance to military health:

- Use of military or Veteran populations, biospecimens, data/databases, or programs in the proposed research. If the proposed research involves access to active-duty military and/or VA 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.
- Collaboration with Department of Defense (DOD) or Department of Veterans Affairs (VA) investigators. Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing melanoma research that is of significance to the Service Members, Veterans, and/or their families.
- Explanation of how the project addresses an aspect of melanoma research that has relevance, or is unique, to Service Members, Veterans, and/or their families.

**Preclinical Research:** All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and,

ultimately, reported. The ARRIVE guidelines can be found at <https://arriveguidelines.org/arrive-guidelines>.

**Metastatic Cancer Task Force:** 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 FY23 MRP priorities.

**Award Basics:** 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.

The anticipated direct costs budgeted for the entire period of performance for an FY23 MRP FPA-RM Award should not exceed **\$2,000,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$6.4M to fund approximately two Focused Program Award – Rare Melanomas 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 FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.*

### **General regulatory considerations:**

**Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DOD-funded research involving new and ongoing research with human

data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), 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 application submission is **not** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of **all required and complete** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page [https://mrhc.health.mil/index.cfm/collaborate/research\\_protections/hrpo](https://mrhc.health.mil/index.cfm/collaborate/research_protections/hrpo) for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research **must** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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 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 a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219.

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

***Clinical research*** encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies. (2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research



that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual. **Note:** Studies that meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#) are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

**Research Involving Animals:** All research funded by the FY23 FPA-RM involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO 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 organizations 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:*** An 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.

**The 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 PI must be an independent investigator at or above the level of Associate Professor (or equivalent).

- The PI is required to devote a minimum of 10% effort to this award.

- An investigator may be named as the PI on only one FY23 MRP FPA-RM application.

The Project Leader for each complementary and synergistic research project must be an independent investigator at or above the level of Assistant Professor (or equivalent).

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

The CDMRP strongly 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).*

*Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.*

### **II.D.1. eBRAP and Grants.gov**

The electronic Biomedical Research Application Portal (eBRAP) (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

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

***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.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 eBRAP 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 eBRAP 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/>).

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](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 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, including the Project Leader(s), and key personnel associated with the application.

[FY23 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](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 overarching question and the research projects that will address the question. Identify the Project Leader(s) and any rare melanoma patient community collaborators (optional) that will serve as an advisor/consultant for the research effort. 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 a full application 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://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>  |  |
| <p>Download application package components for HT9425-23-MRP-FPA-RM from Grants.gov (<a href="https://grants.gov">https://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.</p>  | <p>Download application package components for HT9425-23-MRP-FPA-RM from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</p>  |
| <b>Full Application Package Components</b>   |  |
| <p><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>  | <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> </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> </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> |
| <b>Application Package Submission</b>  |  |
| <p><b>Create a Grants.gov Workspace.</b><br/>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></p>   | <p><b>Submit package components to eBRAP</b> (<a href="https://ebrap.org">https://ebrap.org</a>).</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</p>  |

| Extramural Submissions  | Intramural DOD Submissions   |
|---|--|
| <p>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 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>Do not password protect any files of the application package, including the Project Narrative.</b></p> | <p>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>Do not password protect any files of the application package, including the Project Narrative.</b></p>  |
| <b><u>Application Verification Period</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>with the exception of the Project Narrative and Research &amp; Related Budget Form.</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>with the exception of the Project Narrative and Research &amp; Related Budget Form.</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> |
| <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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (25-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information 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 program in detail using the outline below.

**Overall Program:** Provide a *brief* description of the comprehensive effort. Applicants should propose at least two, but no more than three research projects that address a critical unmet need relevant to rare melanoma research and/or patient care. Summarize the areas of synergy across the proposed research projects. (A *detailed* description of the Overarching Question and each investigator’s roles and responsibilities will be included in [Attachment 6, Overarching Question Statement](#).)

**Research Plan:** Provide the following details for each proposed research project, organizing each project clearly and separately. *Start each research project on a new page.*

- **Title:** Provide a title for each research project.



- **Project Leader:** Identify the Project Leader and any key personnel, as appropriate.
- **Background:** Present the strong scientific rationale to support the proposed research project and its feasibility, as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. As appropriate for the proposed research project, provide sufficient preliminary data to support the feasibility of work proposed. A research project proposing a clinical trial *must* include preliminary data. Any unpublished, preliminary data provided should originate from the laboratory of the Project Leader or a member of the research team.
- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective to be reached.
- **Specific Aims:** State the specific aims of the research project.
- **Research Strategy and Feasibility:** Describe the experimental design, methodology, and analyses, including appropriate controls, in sufficient detail for evaluation. Describe how the studies are designed to achieve the project aims. Address potential problem areas and present alternative methods and approaches.
  - If applicable, clearly describe the statistical plan and the rationale for the statistical methodology. Describe an appropriate power analysis, how it supports the sample size, and how it adequately represents an assessment of the population or subpopulation proposed. If the power analysis was not used to determine the study population numbers, justify why the power analysis is not essential to the statistical evaluation. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations and/or the power of the proposed studies during review of the application. Include a description of the statistical expertise available to support the analysis.
  - If cell lines are to be used, justify why the proposed cell line(s) were chosen and clearly articulate the source(s) of the proposed cell line(s).
  - If animal studies are proposed, including the use of patient-derived xenograft models, justify why the proposed animal model was chosen and clearly articulate the source of the model(s). Describe how the animal studies will be conducted in accordance with the Animal Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.
  - If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human subjects will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of subjects, and for acquiring any additional research resources necessary for conducting the proposed research project.

- For research projects that propose clinical research, 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 specimens/subjects. For clinical research other than a clinical trial, see [Attachment 2](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the research project. For clinical trials, see [Attachment 10](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the trial.

***If a research project requests funds for a clinical trial, details regarding the Clinical Trial Strategy must be described in [Attachment 10](#).***

- **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 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 demonstrating 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 the 2 CFR 200.315, “Intangible Property.”
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource(s) to be made publicly available as a result of the proposed research projects. Describe how data and resources generated during the performance of the overall program will be shared with the rare melanoma research community. Include the name of the repository(ies) where scientific data and/or resources arising from the overall program will be archived, if applicable. If a public repository(ies) will not be used for data and/or resource sharing, provide justification. Provide a milestone plan for data/results dissemination, including when data and resources will be made available to other users. 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.
- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c Enclosure 3, [DoD Instructions 3200.12](#).
  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.
  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.
- **Inclusion Enrollment Plan (only required in Attachment 2 if clinical research other than a pilot clinical trial is proposed):** As applicable, *for each research project that proposes clinical research*, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. Research projects only utilizing human biospecimens or data sets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from

this requirement. The Public Health Service (PHS) Inclusion Enrollment Report is a three-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 (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects): 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.

Clarity and completeness within the space limits of the technical abstract are highly important. ***Technical abstracts must be provided for the overall program, as well as each individual research project, with each abstract starting on a new page.***

The technical abstract for the ***overall program*** should include the following elements as outlined below.

- **Overarching Question:** State the overarching question that will be addressed by the research plan and describe how it will address a critical unmet need for the rare melanoma community.
- **Research Team:** Describe the research team assembled by the PI, including how the expertise and resources of each member, including the PI, will combine to create a robust collaboration.
- **Research Plan:** Provide a brief description of the proposed research projects.
- **Impact:** Describe the potential impact of the proposed effort on the health and well-being of Service Members, Veterans, their families, and all people impacted by the rare melanoma(s) being studied in the proposed research.

The technical abstracts for the *individual research projects* should include the following elements as outlined below.

- **Title:** Provide the title of research project.
  - **Background:** Present the scientific rationale behind the proposed research project.
  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Describe the study design, including the model system(s) that will be used and appropriate controls.
  - **Impact:** Describe how the proposed research project will make an important contribution for the rare melanoma field(s) being studied.
- **Attachment 4: Lay Abstract (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects): 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 outlines below. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the rare melanoma consumer community. Avoid overuse of acronyms and abbreviations, where possible.

***Lay abstracts must be provided for the overall program, as well as each individual research project, with each abstract starting on a new page. ALL lay abstracts should be written using language that will be readily understood by readers without a background in science or medicine.***

The lay abstract for the *overall program* should explain how the proposed effort addresses a critical unmet need relevant to the rare melanoma community, describe the overall question to be addressed, and summarize the ultimate applicability and impact of the research for the rare melanoma community. Include how the proposed research will benefit Service Members, Veterans, their families, and the American public.

The lay abstracts for the *individual research projects* should include the following elements.

- Describe the scientific rationale, objective, and aims for *each* of the proposed research projects.

- For *each* proposed research project, describe the applicability of the research to rare melanoma patients and survivors.
  - What types of patients will the proposed research help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - If the research is too basic for near-term clinical applicability, describe the interim outcomes expected by the end of the period of performance and their applicability to the field of rare melanoma research and/or patient care. What is a reasonable expectation for success for the research project? Basic research should have an ultimate goal of advancing the rare melanoma field and/or impacting patient care.
  - Describe the short- and long-term goals that are related to rare melanoma patient care, outcomes, or survivorship.
- **Attachment 5: Statement of Work (seven-page limit): Upload as “SOW.pdf”.** The suggested SOW format and recommended strategies for assembling the SOW are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).

For the FY23 MRP FPA-RM, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort. The SOW must be in PDF format prior to attaching.

An individual SOW should be included for the overall program and for each research project. Start each SOW on a new page and ensure the title of the research project is listed. If individual documents are created, combine and upload as a single PDF.

The SOW for the overall program should outline the key milestones and communication plans described in the Implementation Plan.

Each research project SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks related to the major tasks and milestones within the period of performance. *The SOWs should describe only the work for which funding is being requested by this application.*

- **Attachment 6: Overarching Question Statement (three-page limit): Upload as “Question.pdf”.**

**Overarching Question:** Describe the overarching question to be addressed, and justify how it addresses a *critical unmet need relevant to rare melanoma research and/or patient care*. Clearly articulate the rationale for the overarching question; include relevant literature citations as appropriate. Clearly explain how the proposed research projects are not dependent upon each other but are interrelated and synergistic with each other and will address the overarching question in unique but complementary ways. Articulate how the proposed program is multidisciplinary and will advance toward a solution that would not be possible through individual efforts.

**Research Team:** Describe how the PI’s research experience, leadership skills, and commitment to making an impact in rare melanoma research and/or patient care demonstrate qualifications necessary to coordinate this collaborative effort. Describe the qualifications of the Project Leader(s) and how those qualifications are appropriate for the completion of the proposed research.

Describe the roles and responsibilities of the PI and each Project Leader, as well as their intellectual contribution to the proposed program. Describe how the overall program depends on each investigator’s unique skills and how the assembled expertise and resources will create a robust, synergistic collaboration necessary to address the overarching question. Provide the time commitment for the PI and each Project Leader and justify that the committed time is appropriate for the completion of the proposed research. The PI is required to devote a minimum of 10% effort to this award.

**Implementation Plan:** Provide an implementation plan for completing the proposed research projects within the proposed period of performance that identifies critical milestones and outlines the knowledge, resources, and/or technical innovations that will be utilized to achieve the stated milestones. Describe how individual research project performance will be assessed during the course of the award, including progression toward defined milestones, realization of study objectives, and success in addressing the overarching question.

Describe plans for communication, decision-making, allocation of resources, coordination of results, and data sharing among all investigators and organizations participating in the project.

*A figure may be included within the three-page limit.*

- **Attachment 7: Impact Statement (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects): Upload as “Impact.pdf”.**

*Impact statements must be provided for the overall program, as well as each individual research project, with each impact statement starting on a new page. ALL impact statements should be written using language that will be readily understood by readers without a background in science or medicine.*

The impact statement for the *overall program* should include the following elements.

- Explain how the overall program will make important scientific advances for the rare melanoma patient community(ies) affected by the proposed research.
- Explain how the overall program will promote greater understanding of the causes and progression of rare melanomas and/or will promote the development of improvements in prevention, detection, diagnosis, treatment, and/or quality of life for the rare melanoma community.

- Describe the long-term vision for how the outcomes from the overall program will impact the lives of rare melanoma patients.

The impact statements for the *individual research projects* should include the following elements.

- Describe the relevance of the research project on the health and well-being of Service Members, Veterans, their families, and all people impacted by the rare melanoma(s) being studied in the proposed research project.
  - For projects that propose a clinical trial, explain how the targeted patient population will benefit from the proposed intervention and how the outcome(s) will ultimately be translated to rare melanoma patients.
  - Describe how the anticipated outcome(s)/product(s) resulting from the research project will impact rare melanoma research and/or patient care in the short term.
- **Attachment 8: Post-Award Transition Plan (four-page limit): Upload as “Transition.pdf”.**

Describe the methods and strategies necessary to move the anticipated research outcomes of the overall program (e.g., intervention, product, methodology, finding) to the next phases of development (e.g., clinical trials, commercialization, and/or delivery to the civilian or military market) following the successful completion of the proposed effort. PIs are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. PIs are encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving any interventions, products, etc. into the next phase of development. The transition plan should address the components listed below, as appropriate:

- Describe the outcomes expected upon completion of the proposed research projects, which include knowledge products, clinical products for development, etc. Outcomes should be specific and measurable and specify the intended end user.
- Outline the next logical steps to advance the research outcomes to clinical implementation. Include details regarding Regulatory Agency (e.g., FDA) approval, as appropriate.
- Provide a timeline with defined milestones and deliverables describing the expected post-award progress of the research outcomes with the end goal of distributing the findings/interventions to the rare melanoma patient community.
- Describe collaborations and other resources that are in place or will be established during the period of performance to execute the next steps to advance the research outcome to the next phase of development and eventual clinical implementation (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources).



- Detail the funding strategy necessary to transition to the next level of investigation, development, and/or commercialization. This may include commercial sponsorship, venture capital, federal or non-federal funding opportunities, etc.
- Assess the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcomes into clinical practice.
- If applicable, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the rare melanoma community.
- **Attachment 9: Rare Melanoma Patient Community Collaboration, if applicable: Combine multiple documents, including letters of collaboration, into one PDF and upload as “Community.pdf”.**
  - **Rare Melanoma Patient Community Collaboration Statement (two-page limit):** Applicants that propose to collaborate with the rare melanoma patient community should provide a Rare Melanoma Community Collaboration statement that addresses the following:
    - Describe the collaborative research approach that will be used (collaborating with at least one rare melanoma patient advocate, partnering with a rare melanoma community-supporting organization, etc.), including a justification for the approach.
    - Provide the name of the patient advocate(s) and their affiliation(s) and/or the name(s) of the community-supporting organization(s) who will provide advice and consultation throughout the planning and implementation of the research project.
    - Indicate the input from the rare melanoma patient community partner that has already been and/or will be captured and how this input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
  - **Letter(s) of Rare Melanoma Patient Community Collaboration (two-page limit per letter):** Provide a letter signed by each rare melanoma patient community collaborator and/or rare melanoma community-supporting organization confirming their role and commitment to participate on the research team. If a community-supporting organization will be engaged, the letter of commitment should be signed by both the organization point of contact leading the collaboration and the organization’s leadership endorsing the collaboration. The letter should include the qualifications and background of the rare melanoma patient community collaborator(s) and describe the relevance of those qualifications to the proposed research.

- **Attachment 10: Clinical Trial Strategy, if applicable (no page limit): Combine multiple documents into one PDF and upload as “Clinical.pdf”. *The clinical trial strategy is only applicable and required for applications that propose a clinical trial.***
  - Describe the rationale for the proposed clinical trial. Demonstrate how the proposed clinical trial is supported by strong preliminary data and relevant literature citations. Provide a description of the intervention, and the endpoints to be measured. Describe how the proposed intervention compares with currently available interventions and/or standards of care. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications, as appropriate.
  - Articulate the type of clinical trial to be performed (e.g., randomized, cohort, case-control, cross-sectional) and outline the proposed methodology in sufficient detail to show a clear course of action. Provide detailed plans for initiating the clinical study no later than 12 months after the award date, including FDA Investigational New Drug/Investigational Device Exemption (IND/IDE), or international regulatory agency, application submission plans no later than 60 days after the award date, if applicable. Define the study population and indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the informed consent process. Include a justification for the plans and alternatives strategies if issues arise.
  - Describe the composition of the clinical trial team. Provide details on how the Project Leader, study coordinator, statistician, and/or other key project personnel possess the appropriate expertise for conducting the proposed clinical trial.
  - 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. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The PHS Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, if applicable.
- **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](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 a biographical sketch for each Project Leader.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - Include previous/current/pending support for each Project Leader.

**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.

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. *As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.* Refer to the

General Application Instructions, Section III, for further information regarding Grants.gov requirements.

#### **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 **4** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$2.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with 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 **4** years.

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

- Travel costs for the PI and up to two additional members of the research team to attend a 1-day DOD MRP Milestone Meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting should be included in year 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- If the research team includes rare melanoma patient community collaborator(s), travel costs may be requested for one rare melanoma patient community collaborator to attend the 1-day DOD MRP Milestone Meeting.
- Travel in support of multidisciplinary collaborations.
- Costs for up to three investigators to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to disseminate project results from the FY23 MRP FPA-RM.

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:

#### **Scored review criteria for the overall program:**

- **Overarching Question and Implementation Plan**
  - To what extent the applicant describes the overarching question and justifies how it addresses a critical unmet need relevant to the rare melanoma research and/or patient care.
  - To what extent the applicant clearly articulates the rationale for the overarching question.
  - To what extent the research projects are not dependent upon each other but are interrelated and synergistic, and will address the overarching question in unique but complimentary ways, including how the program will advance toward a solution through a multidisciplinary approach.
  - To what extent the areas of synergy across the proposed research projects are summarized.
  - To what extent the implementation plan identifies critical milestones and outlines the knowledge, resources, and/or technical innovations that will be utilized to achieve the stated milestones.
  - To what extent the implementation plan describes how individual research project performance will be assessed during the course of the award.
  - To what extent the implementation plan describes plans for communication, decision-making, allocation of resources, coordination of results, and data sharing among all investigators and organizations participating in the overall program.

- **Research Team and Key Personnel**

- To what extent the PI's experience, leadership skills, and commitment to making an impact in rare melanoma research and/or patient care demonstrate qualifications to coordinate the collaborative effort.
- To what extent each Project Leader's qualifications are described and appropriate for the completion of the proposed research.
- To what extent the roles and responsibilities of the PI and each Project Leader and their intellectual contributions contribute to the overall program.
- To what extent the overall program depends on the unique skills of each investigator.
- To what extent the assembled expertise and resources will create a robust, synergistic collaboration.
- If applicable, to what extent the composition of the clinical trial team is well-described, including details on how the team possesses the appropriate expertise in conducting clinical trials.
- Whether the time commitment of each Project Leader is provided and is appropriate for the completion of the proposed research.
- Whether the PI will devote a minimum of 10% effort to this award.
- Whether appropriate letters of support and collaboration indicate that the research team has the support and resources necessary for the proposed effort.
- Based on the biographical sketches, to what extent the Project Leader's and associated key personnel's backgrounds are appropriate to complete the proposed research projects.

- **Post-Award Transition Plan**

- To what extent the post-award transition plan describes the outcomes expected upon completion of the research projects.
- To what extent the plan outlines the next logical steps to advance the research outcomes to clinical implementation.
- Whether the plan provides a timeline with defined milestones and deliverables describing the expected post-award progress of the research outcomes with the end goal of distributing the findings/interventions to the rare melanoma patient community.
- To what extent the plan describes collaborations and other resources that are in place or will be established during the period of performance to execute the next steps to advance the research outcome to the next phase of development and eventual clinical implementation.



- To what extent the plan describes the funding strategy necessary to transition the outcomes of the research projects to the next level(s) of development and/or commercialization.
  - To what extent the plan assesses the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcomes into clinical practice.
  - If applicable, to what extent the applicant discusses ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported under this overall program.
- **Impact**
    - To what extent the overall program will make important scientific advances for the rare melanoma patient community(ies) affected by the proposed research.
    - To what extent the application describes how the overall program will promote greater understanding of the causes and progression of rare melanomas and/or promote the development of improvements in prevention, detection, diagnosis, treatment, and/or quality of life for the rare melanoma community.
    - To what extent the application articulates a long-term vision for how the outcomes from the overall program will impact the lives of rare melanoma patients

**Scored review criteria for each individual research project:**

- **Research Strategy and Feasibility**
  - To what extent the scientific rationale supports the project and its feasibility, as demonstrated by logical reasoning, a critical review and analysis of the literature, and, as appropriate for the proposed research project, sufficient preliminary data.
  - If a clinical trial is proposed, to what extent appropriate preliminary data are provided.
  - To what extent the hypothesis or objective, experimental design, methodology, and analyses are developed and support successful completion of the specific aims.
  - To what extent the application acknowledges potential problems and addresses alternative methods and approaches.
  - If applicable, to what extent the statistical plan is appropriate for the proposed research, and the applicant provides sufficient information to allow thorough evaluation of all statistical calculations and/or the power of the proposed studies.
  - If applicable, whether the use of the proposed cell lines is justified.

- If applicable, to what extent the proposed animal studies are designed to achieve the research objectives, to include the use of appropriate models.
  - If applicable, to what extent the applicant demonstrates the availability of human data sets, human anatomical substances, and/or human subjects, including a detailed plan for the acquisition of samples/resources and/or recruitment of human subjects necessary for conducting the proposed research.
  - 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.
- **Impact**
    - To what extent the anticipated outcomes/products from each research project will impact rare melanoma research and/or patient care in the short term.
    - To what extent the proposed research is relevant to the health and well-being of Service Members, Veterans, their families, and all people impacted by the rare melanoma(s) being studied in the proposed research project.
    - If applicable, to what extent that the targeted patient population will benefit from the outcomes of a proposed clinical trial.
    - If applicable, to what extent the applicant explains how the outcomes of a proposed clinical trial will be translated to rare melanoma patients.
  - **Clinical Strategy (*only applicable if a clinical trial is proposed*)**
    - To what extent the rationale for the clinical trial is described and is supported by strong preliminary data and relevant literature citations.
    - To what extent the applicant describes how the intervention compares with currently available interventions and/or standard of care, including a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications, as appropriate.
    - To what extent the type of clinical trial is articulated and the proposed methodology is outlined in sufficient detail to show a clear course of action.
    - If applicable, to what extent detailed plans for initiating the clinical study no later than 12 months after the award date, including FDA IND/IDE or international regulatory agency application submission plans no later than 60 days after the award date are described.

- To what extent the study population, recruitment plans, inclusion/exclusion criteria, and the informed consent process are described and will meet the needs of the proposed clinical trial.
- To what extent potential challenges and alternative strategies are addressed.
- 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 the proposed clinical trial was initiated using other funding prior to this application, how well the history and background of the clinical trial, including the source of prior funding, are explained. Whether it is clear which portions of the study would be supported with funds from this award.
- To what extent data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, or international regulatory agency, is described, if applicable.

**The following *unscored criteria* will also contribute to the evaluation of the overall application:**

- **Data and Resource Sharing**

- To what extent the plan for sharing project data and research resources is appropriate and reasonable.
- If applicable, whether specific repository(ies) are named where scientific data and/or resources arising from the project will be archived.

- **Budget**

- Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
- Whether there may be overlap with existing or pending awards of the PI or Project Leader(s).
- To what extent the budget is appropriate for the proposed research projects.

- **Rare Melanoma Community Collaboration (if applicable)**

- To what extent a collaborative research approach is described.
- Whether a rare melanoma patient advocate and/or a rare melanoma community-supporting organization is named.

- To what extent application describes the input from the rare melanoma patient community partner(s) that has already been and/or will be captured.
- To what extent the application describes how the rare melanoma community input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.
- Whether a letter (or letters) of support from the rare melanoma community collaborator(s) is provided.
- **Environment**
  - To what degree the scientific environment is appropriate for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.
  - Whether the lay abstract and impact statement are written with clarity for persons without a background in science or medicine.

#### **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 FY23 MRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relevance to military health
  - 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.health.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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the 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 FY23 funds are anticipated to be made no later than September 30, 2024. 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 the 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, other non-profit or for-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.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis 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](#) and the [USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions](#) for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

## 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 may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to 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. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

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

### **II.G.1. eBRAP 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 eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). 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 eBRAP 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 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

### **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 FY23 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 FY23 MRP Programmatic Panel members can be found at <https://cdmrp.health.mil/mrp/panels/panels23>.*
- 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 FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security.
- Submission of the same research project to different funding opportunities within the same program and fiscal year. Refer to [Section II.D, Application and Submission Information](#).
- The PI or any named Project Leader does not meet the eligibility criteria.
- The applicant organization submits more than one FPA-RM application with the same investigator named as the PI.
- The main subject of the research does not address a critical unmet need relevant to rare melanomas.
- The main subject of the research is non-melanoma skin cancers.
- An application that proposes a clinical trial where the Clinical Trial Strategy ([Attachment 10](#)) is missing.

#### **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"   |           |
|  | Overarching Question Statement: Upload as Attachment 6 with file name "Question.pdf"   |           |
|  | Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"   |           |
|  | Post-Award Transition Plan: Upload as Attachment 8 with file name "Transition.pdf"   |           |
|  | Rare Melanoma Community Collaboration: Upload as Attachment 9 with file name "Community.pdf" if applicable                       |           |
|  | Clinical Trial Strategy: Upload as Attachment 10 with file name "Clinical.pdf" if applicable                                     |           |
|  | Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf"                         |           |
|  | 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  |           |
| Research & Related Senior/Key Person Profile (Expanded)  | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field  |           |

| Application Components   | Action   | Completed |
|--|--|-----------|
|  | 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   |
| DOD      | Department of Defense   |
| DoDGARs  | Department of Defense Grant and Agreement Regulations                                     |
| eBRAP    | Electronic Biomedical Research Application Portal   |
| EC       | Ethics Committee  |
| ET       | Eastern Time  |
| FAD      | Funding Authorization Document  |
| FAPIIS   | Federal Awardee Performance and Integrity Information System                              |
| FDA      | U.S. Food and Drug Administration   |
| FPA-RM   | Focused Program Award – Rare Melanomas  |
| FY       | Fiscal Year   |
| IACUC    | Institutional Animal Care and Use Committee   |
| IDE      | Investigational Device Exemption  |
| IND      | Investigational New Drug  |
| IRB      | Institutional Review Board  |
| LOI      | Letter of Intent  |
| M        | Million   |
| MB       | Megabytes   |
| MIPR     | Military Interdepartmental Purchase Request   |
| OHARO    | Office of Human and Animal Research Oversight (previously Office of Research Protections) |
| OHRO     | Office of Human Research Oversight (previously Human Research Protection Office)          |
| ORCID    | Open Researcher and Contributor ID, Inc.  |
| PDF      | Portable Document Format  |
| PHS      | Public Health Service   |
| PI       | Principal Investigator  |
| SAM      | System for Award Management   |
| SOW      | Statement of Work   |
| STEM     | Science, Technology, Engineering, and/or Mathematics                                      |
| UEI      | Unique Entity Identifier  |
| URL      | Uniform Resource Locator  |
| USAMRAA  | U.S. Army Medical Research Acquisition Activity   |

|         |  |
|---------|--|
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC     | United States Code                                 |
| VA      | U.S. Department of Veterans Affairs                |