

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Melanoma Research Program

Mid-Career Accelerator Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-MRP-MCAA

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

With the exception of studies investigating rare melanomas, the FY23 MRP is not requesting research into established macrometastatic disease, metastatic disease using established cell line models, or treatment of macrometastatic disease.

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

The proposed research must be relevant to Service Members, Veterans, other beneficiaries of the Military Health System (MHS), and the American public.

II.A.1. FY23 MRP Focus Areas

The MRP is seeking to support research that aims to inhibit melanoma earlier in the disease progression to prevent metastasis, reduce suffering, and increase survival. To be considered for funding, applications for the FY23 MRP Mid-Career Accelerator Award (MCAA) **must** address at least one of the following FY23 MRP Focus Areas.

Prevention: The MRP challenges the research community to expand the concept of melanoma prevention to include improving detection and monitoring capabilities, as well as inhibiting the initiation of melanoma, the early dissemination, the emergence from tumor dormancy, and the development of metastases. The FY23 MRP Focus Areas that encourage research into the role of prevention throughout the disease process are:

- Identify and understand risk factors and biomarker determinants for melanoma, including rare subtypes.
- Develop prediction and surveillance tools for distinguishing patient populations and/or early tumors at risk for second primary, recurrence, metastasis, and/or treatment toxicity.

- Develop new tools for the detection of melanoma, which includes easily accessible technology (beyond the dermoscope) for primary care physicians, dermatologists, oncologists, and/or pathologists.
- Understand how precursor lesions evolve, and/or how environmental/endogenous factors influence melanomagenesis and/or early dissemination.
- Identify how the tumor microenvironment and/or microbiome impacts tumor initiation, response to therapy, progression, recurrence, and/or dormancy.
- Delineate the cellular and/or molecular mechanisms that influence metastatic spread (e.g., site-specific adaptations), recurrence, and/or dormancy.
- Develop new preclinical models of melanomagenesis, early dissemination, and progression that more faithfully represent the disease progression observed in humans.

Rare melanomas: Rare melanoma subtypes (e.g., uveal, acral, mucosal, pediatric melanomas) can have distinct characteristics compared to cutaneous melanoma, which makes up the majority of melanoma diagnoses. This has led to a variety of prevention, diagnosis, and treatment challenges. Furthermore, rare melanomas are less well-studied than cutaneous melanoma, resulting in a dearth of knowledge across the entire cancer research spectrum. The following FY23 MRP Focus Area encourages research relevant to rare melanoma research and patient care:

- Address unmet needs across the entire cancer research spectrum (biology, etiology, prevention, early diagnosis and detection, prognosis, treatment, and survivorship) for rare melanomas.

Survivorship: Increasing availability of effective treatment options for advanced melanoma over the last decade means that patients are living longer. This has created a need to address the long-term effects of treatment toxicities, fertility issues, and the overall quality of life of patients living with melanoma. The following FY23 MRP Focus Area encourages research relevant to these important survivorship issues:

- Address the physical and psychological impacts of a melanoma diagnosis, symptom trajectories, adverse effects of treatment, and other outcomes that affect individuals with melanoma and their family members.

II.A.2. Award History

The MRP MCAA mechanism was first offered in FY20. Since then, 49 compliant, full applications have been received, and 11 were recommended for funding.

II.B. Award Information

The MRP MCAA supports independent, mid-career investigators conducting impactful research in the field of melanoma. The MCAA presents an opportunity for mid-career investigators with prior experience in melanoma research and/or patient care to obtain funding to continue

performing impactful research that will also accelerate their career and establish them as leaders in the melanoma field. *Preliminary data relevant to melanoma are required.*

Key aspects of the MCAA:

Principal Investigator: The Principal Investigator (PI) must be a mid-career researcher or physician-scientist at the level of Assistant or Associate Professor (or equivalent). The PI must be *at least 7 years from obtaining their first faculty-level appointment. Instructors and full professors (or equivalents) are not eligible.* The PI must demonstrate previous receipt of at least one peer-reviewed source of extramural funding. The PI's record of accomplishments (publications, presentations, patents, etc.) and the proposed research will be evaluated regarding the PI's potential for contributing to the melanoma field.

Impact: The impact of the proposed research must relate to at least one of the FY23 MRP Focus Areas in [Section II.A.1](#). Impactful research, including basic research, should expedite the advancement of promising ideas towards clinical utility. The application must articulate the short- and long-term impact the proposed work will have on *melanoma research and/or patient care*.

Continuity Plan: The goal of the MCAA is to support investigators who have laid the foundation for becoming leaders in the melanoma field and who intend to advance the state of the science in melanoma. The Continuity Plan ([Attachment 7](#)) should explain how the PI has the potential to establish themselves as a leader in the melanoma field, beyond their own laboratory or institution. Additionally, it should describe the PI's plan for the continued development of their research program to benefit *melanoma research and/or patient care*.

Synergy with the MRP Melanoma Academy: To enhance networking and collaboration options for both the MCAA PI and MRP Melanoma Academy Scholars, MCAA PIs will be encouraged to participate in Melanoma Academy activities (e.g., networking events, seminars hosted by the MRP Melanoma Academy Leadership) as appropriate. MCAA PIs will be *required* to attend one meeting hosted by the MRP Melanoma Academy Leadership during the second year of the MCAA to present project information or disseminate project results. Additional information about the Melanoma Academy can be found on the [MRP website](#).

Other important considerations:

Melanoma Resources: When appropriate and feasible, PIs are encouraged to take advantage of existing, well-characterized data and specimens. Examples of such resources are listed below. PIs are encouraged to explore the utility of these and/or other resources to ensure the use of the most appropriate data and/or models to conduct impactful melanoma research. The list is not intended to be all-inclusive, and the information provided below, including external links and references, is not to be construed as endorsement by the Department of Defense (DOD), CDMRP, or MRP.

- [National Cancer Institute \(NCI\) Patient-Derived Models Repository \(PDMR\)](#). The PDMR is a national repository of Patient-Derived Models (PDMs) comprised of patient-derived xenografts (PDXs), *in vitro* patient-derived tumor cell cultures (PDCs) and cancer-associated fibroblasts (CAFs), as well as patient-derived organoids. In addition to model generation,

NextGen sequencing data are available for all models, as well as DNA, RNA, and flash-frozen fragments for protein extraction from early-passage PDXs. The PDMR's melanoma catalog currently contains 40 PDXs, 28 PDCs, 13 organoids, and 6 CAF cultures.

- [Human Cancer Models Initiative \(HCMI\)](#). The goal of the HCMI is to create up to 1,000 patient-derived next-generation cancer models such as organoids, conditionally reprogrammed cells, neurospheres, or optimal growth condition models as a community resource. The HCMI aims to provide the models' case-associated data, which include quality-checked clinical, biospecimen, and molecular characterization data from the models, the tissues from which they were derived, and normal tissues, when available. Available harmonized data are accessible through NCI's Genomic Data Commons.
- [NCI-funded Skin Specialized Programs of Research Excellence \(SPOREs\)](#). There are currently five skin SPOREs whose programs focus predominantly on melanoma. Historically, each SPORE site includes a biospecimen core.
- [Department of Veterans Affairs \(VA\) Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases \(VA SHIELD\)](#). The VA SHIELD is a comprehensive, secure biorepository of specimens and associated data that provides researchers and clinicians with high-quality biosamples and comprehensive associated medical and sample data to accelerate the discovery-to-therapy pipeline for the benefit of Veterans. **NOTE:** These specimens and data are available ONLY to authorized VA investigators.
- [Million Veteran Program](#). The Million Veteran Program (MVP) is the nation's largest genomic biorepository of Veteran data and is one of the most diverse cohorts of any genetic research program in the world. **NOTE:** Access to MVP data is limited to ONLY VA-affiliated researchers.
- [Patient-Derived Cancer Models](#). Cancermodels.Org provides harmonized and integrated model attributes to support consistent searching for PDX, organoid, and cell line models and facilitate researchers' search for models and associated data across multiple commercial and academic resources.
- [The CURE OM VISION Platform](#). The CURE OM VISION Platform is a patient-powered ocular melanoma (OM) research project funded and sponsored by the Melanoma Research Foundation's CURE OM initiative. The registry launched in the U.S. in May 2021 and was made available to participants worldwide soon thereafter. The CURE OM initiative's patient community and collaborators are now actively participating, sharing data, and joining researchers in the work towards more effective treatments and, one day, a cure.
- [The RARE® Registry](#). The RARE® Melanoma Registry is an initiative led by the Melanoma Research Alliance for patients with acral and mucosal melanoma. It provides a free, interactive, web, and mobile-friendly tool to share information, experiences, and disease history; advance research and awareness; and get potential matches to clinical trials.

Relevance to Military Health: The advancement of knowledge in melanoma research, patient care, and/or treatment options in the MHS is critical. Therefore, the MRP seeks to support research that is relevant to the healthcare needs of Service Members, Veterans, and their

families. PIs 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 DOD or 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 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).

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 guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) 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>.

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 Mid-Career Accelerator Award should not exceed **\$725,000**. 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 \$3.48M to fund approximately three Mid-Career Accelerator Award applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this 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://mrdc.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 NOT allowed under the MCAA.

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.

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 MRP MCAA 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 investigator must:

- Be at the level of Assistant or Associate Professor (or equivalent).
 - Instructors and Full Professors (or equivalents) are **NOT** eligible.
- Be at least 7 years from their first faculty-level appointment at the time of application submission.
- Be able to demonstrate previous receipt of at least one peer-reviewed extramural source of funding.

An investigator may be named on only one MCAA application as a PI.

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

The CDMRP 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 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 or 301-682-5507 to request a change in designation.

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

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after

submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

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

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

[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 or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY23 MRP Focus Area(s) (listed in [Section II.A.1](#)) under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit 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 |
|--|--|
| Application Package Location | |
| Download application package components for HT9425-23-MRP-MCAA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission. | Download application package components for HT9425-23- MRP-MCAA from eBRAP (https://ebrap.org). |
| Full Application Package Components | |
| SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information. | <p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p> |
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form | <p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p> |
| Application Package Submission | |
| <p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time</p> | <p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password</i></p> |

| Extramural Submissions | Intramural DOD Submissions |
|---|---|
| <p>to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: 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 <i>prior to</i> the application submission deadline. Do not password protect any files of the application package, including the Project Narrative.</p> | <p><i>protect any files of the application package, including the Project Narrative.</i></p> |
| <u>Application Verification Period</u> | |
| <p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p> | <p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p> |
| Further Information | |
| <p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p> | <p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p> |

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

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

- **Attachment 1: Project Narrative (10-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (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 project in detail using the outline below.

- **Background:** Present the strong scientific rationale behind the proposed research, as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. Preliminary data such as published or unpublished results from the laboratory and/or clinic of the PI or collaborators named on this application must be included; *inclusion of preliminary data relevant to melanoma is required.* Describe any important discoveries, outcomes, or advancements that can be attributed to the PI’s previous work in melanoma.
- **Hypothesis and Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** State the specific aims of the study. If the proposed research is part of a larger study, *present only tasks that this award would fund*

- **Research Strategy and Feasibility:** Describe the experimental design (if applicable), methodology, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. 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; including the statistical expertise available to support the analysis.
 - If cell lines are to be used, justify why the proposed cell line(s) are appropriate to achieve the goals the proposed study(ies) and clearly articulate the source(s) of the proposed cell line(s).
 - If animal studies are proposed, including the use of PDX models, justify why the proposed animal model(s) was chosen and clearly articulate the source of the model(s). Describe how the animal studies will be conducted in accordance with the 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 all applications 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. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. ***This award cannot be used to conduct clinical trials.*** For clinical research, see [Attachment 2](#) for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
- **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 and/or access to 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.

- **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **Data and Research Resources Sharing Plan:** Describe the type of data and/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 project will be shared with the 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. 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 if clinical research is proposed*):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) 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 (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should include the following elements as outlined below. Clarity and completeness within the space limits of the technical abstract are highly important.

- **Personnel:** Describe the PI’s background in the melanoma field, addressing important discoveries, outcomes, or advancements attributed to the PI’s work.
 - **Background:** Present the ideas and reasoning behind the proposed work. Describe the preliminary data upon which the study is founded.
 - **Hypothesis/Objective:** State the hypothesis to be tested or 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 project will make an important contribution toward at least one of the FY23 MRP Focus Areas described in [Section II.A.1](#).
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the melanoma consumer community. Avoid overuse of acronyms and abbreviations.

Include the following elements, using language that will be ***readily understood by readers without a background in science or medicine.***

- State the FY23 MRP Focus Area(s) in [Section II.A.1](#) to be addressed by the research project.
- Summarize the scientific rationale, objective, and aims for the proposed.

- Describe the PI’s potential to establish themselves as a leader in the melanoma field.
- Describe the applicability of the research to melanoma patients and/or 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 clinical applicability, describe the interim outcomes expected and their applicability to the field of melanoma. Basic research should have an ultimate goal of advancing the melanoma field and/or impacting patient care.
 - Describe the short- and long-term goals that are related to melanoma patient care, outcomes, or survivorship. How will the proposed research Service Members, Veterans, their families, and the American public?
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested Statement of Work (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 MCAA, refer to either the “*Suggested SOW Strategy Clinical Research*” or “*Suggested SOW Strategy Generic Research*”, whichever format is most appropriate for the proposed effort. The SOW must be in PDF format prior to attaching.

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

Using language readily understood by readers without a background in science or medicine:

- State how the proposed research addresses a critical problem that, if successfully addressed, will have a major impact on at least one of the FY23 MRP Focus Areas in [Section II.A.1](#).
- Outline the anticipated research outcome(s)/product(s) of the proposed research methods, including knowledge products, clinical products for development, etc. Explain how the anticipated outcome(s)/product(s) will impact the melanoma field and/or patient care in the short term.
- Describe the PI’s long-term vision for how their research goals, if accomplished, will advance the state of the science to benefit melanoma patients and/or survivors.
- Describe the relevance of the proposed research to the proposed research on the health and well-being of Service Members, Veterans, their families, and all people affected by melanoma. ***The relevance of all research, including basic, should relate to patient outcomes and how it benefits those affected by melanoma.***

- **Attachment 7: Continuity Plan: (two-page limit): Upload as “Continuity.pdf”.** Explain how the PI has the potential to establish themselves as a leader in the melanoma field, beyond their own laboratory or institution. Articulate the strategies for collaborating with leaders in the melanoma field and/or building multidisciplinary teams to advance the state of the science in melanoma. Identify approaches to expand PI’s knowledge base and put the gained knowledge into action in the melanoma field.

Describe the PI’s plan for the continued development of their research program. Explain the next logical steps necessary to advance the anticipated research outcome(s)/product(s) into the next phase of development or toward clinical utility *for the benefit of melanoma patients*. Describe the collaborations and other resources, including a funding strategy, that are in place or will be established during the MCAA period of performance to execute the next steps to advance the research outcome(s)/product(s). PIs are encouraged to explore developing relationships with their Technology Transfer Office (or equivalent), industry, and/or other funding agencies to facilitate moving any interventions, products, etc. into the next phase of development. If applicable, demonstrate that a plan for intellectual property management is in place.

- **Attachment 8: Statement of Eligibility (one-page limit): Upload as “Eligibility.pdf”.** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met. The letter should verify that the PI is *at least 7 years from their first faculty-level appointment*, (Refer to Section II.C, Eligibility Information.), has independent laboratory space, and has been previously named as PI on at least one peer-reviewed, extramurally funded award.
- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 10: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (MHS facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able

to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

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

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

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf”.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

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

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

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 10](#). (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 **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$725,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.

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

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

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

- Travel costs for the PI to attend one meeting hosted by the [MRP Melanoma Academy Leadership](#) during the second year of the MCAA (place and time to be determined; for planning purposes PIs can provide travel estimates to either the Boston or Houston metropolitan areas). The intent of this travel is to enhance networking and collaboration options for both the Melanoma Academy Scholars and the MCAA PI. It is expected that the PI will present project information or disseminate project results from this FY23 MRP MCAA.

May be requested for (not all-inclusive):

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

Must not be requested for:

- Clinical trial costs

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

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

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**
 - To what extent the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning.
 - Whether preliminary data originating from the laboratory of the PI or collaborator(s) are relevant to melanoma was included.
 - To what extent the hypothesis or objective, experimental design (if applicable), methodology, and analyses are appropriate to achieve the project aims and feasible.

- How well 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.
 - If applicable, whether the use of the proposed cell lines is appropriately justified.
 - If applicable, to what extent the 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 proposed research addresses a critical scientific or clinical issue in at least one of the FY23 MRP Focus Areas in Section II.A.1.
 - How well the anticipated research outcome(s)/product(s) are outlined.
 - To what extent the anticipated outcome(s)/product(s) resulting from the research project will impact the field of melanoma and/or patient care in the short term.
 - To what extent the long-term vision for how the PI's specific career and research goals, if accomplished, will advance the state of the science towards benefiting melanoma patients and/or survivors.
 - To what extent the proposed research is relevant to the health and well-being of Service Members, Veterans, their families, and all people affected by melanoma
 - **Principal Investigator**
 - Whether the PI meets the eligibility requirements.
 - Based on the biographical sketch, to what extent the PI's background is appropriate to accomplish the proposed research and includes prior investigations within the field of melanoma.
 - To what extent important discoveries, outcomes, or advancements can be attributed to the PI's previous work in melanoma.

- Whether the levels of effort based on the budget justification are appropriate for successful conduct of the proposed work.

- **Continuity Plan**

- To what extent the PI explains their potential to establish themselves as a leader in the melanoma field, beyond their own laboratory or institution.
- To what extent the strategies for collaborating with leaders in the melanoma field and/or building multidisciplinary teams to advance the state of the science in melanoma are articulated.
- To what extent the PI identifies approaches to expand their knowledge base and put the gained knowledge into action in the melanoma field.
- To what extent the next logical steps necessary to advance the anticipated research outcome(s)/product(s) into the next phase of development or toward clinical application are explained, including targeted milestones.
- To what extent the plan describes collaborations and other resources, including a funding strategy, that are in place or will be established during the MCAA period of performance to execute the next steps to advance the research outcome(s)/product(s).
- If applicable, whether a plan for intellectual property management is in place.

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

- **Personnel**

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

- **Budget**

- Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
- To what extent the budget is appropriate for the proposed research.

- **Environment**

- To what extent 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
 - Relevance to at least one of the FY23 MRP Focus Areas in Section II.A.1
 - Relative impact
 - Relative potential for the PI to establish themselves as a leader in the melanoma field

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 only allowed 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.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to 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

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

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 propose 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.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application does not address at least one of the FY23 MRP Focus Areas in [Section II.A.1](#).
- The PI is named on more than one MCAA application.
- The main subject of the research is non-melanoma skin cancers.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

| Application Components | Action | Completed |
|--|---|-----------|
| SF424 Research & Related Application for Federal Assistance (extramural submissions only) | Complete form as instructed | |
| Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only) | Complete tabs as instructed | |
| Attachments | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf" | |
| | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf" | |
| | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf" | |
| | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf" | |
| | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf" | |
| | Impact Statement: Upload as Attachment 6 with file name "Impact.pdf" | |
| | Continuity Plan: Upload as Attachment 7 with file name "Continuity.pdf" | |
| | Statement of Eligibility: Upload as Attachment 8 with file name "Eligibility.pdf" | |
| | Representations, applicable (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable | |
| | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable | |
| | Complete form as instructed | |
| Research & Related Personal Data | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field | |
| Research & Related Senior/Key Person Profile (Expanded) | 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 | |

| Application Components | Action | Completed |
|--|--|-----------|
| | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field | |
| | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field | |
| Research & Related Budget (extramural submissions only) | Suggested DOD Military Budget Format, including justification | |
| Budget (intramural submissions only) | Complete form as instructed | |
| Project/Performance Site Location(s) Form | Complete form as instructed | |
| Research & Related Subaward Budget Attachment(s) Form, if applicable | | |

APPENDIX 1: ACRONYM LIST

| | |
|----------|---|
| ACOS/R&D | Associate Chief of Staff for Research and Development |
| ACURO | Animal Care and Use Review Office |
| ARRIVE | Animal Research: Reporting <i>In Vivo</i> Experiments |
| CAF | Cancer-Associated Fibroblast |
| 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 |
| FY | Fiscal Year |
| HCMI | Human Cancer Models Initiative |
| IACUC | Institutional Animal Care and Use Committee |
| IPR | In-Progress Review |
| IRB | Institutional Review Board |
| LOI | Letter of Intent |
| M | Million |
| MB | Megabytes |
| MCAA | Mid-Career Accelerator Award |
| MHS | Military Health System |
| MIPR | Military Interdepartmental Purchase Request |
| MVP | Million Veteran Program |
| NCI | National Cancer Institute |
| OHARO | Office of Human and Animal Research Oversight (previously Office of Research Protections) |
| OHRO | Office of Human Research Oversight (previously Human Research Protection Office) |
| OM | Ocular Melanoma |
| ORCID | Open Researcher and Contributor ID, Inc. |
| PDC | Patient-Derived Tumor Cell Culture |
| PDF | Portable Document Format |
| PDM | Patient-Derived Model |
| PDMR | Patient-Derived Models Repository |

| | |
|-----------|--|
| PDX | Patient-Derived Xenograft |
| PHS | Public Health Service |
| PI | Principal Investigator |
| SAM | System for Award Management |
| SOW | Statement of Work |
| SPORE | Specialized Programs of Research Excellence |
| 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 | Department of Veterans Affairs |
| VA SHIELD | VA Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases |