I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Melanoma Research Program

Melanoma Academy Scholar Award

Announcement Type: Initial

Funding Opportunity Number: HT942524MRPMASA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 29, 2024

- **Application Submission Deadline:** 11:59 p.m. ET, August 26, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, September 3, 2024

- **Peer Review:** November 2024

- **Programmatic Review:** February 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Melanoma Research Program (MRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the MRP in 2019 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the MRP from FY19 through FY24 totaled $140 million (M). The FY24 appropriation is $40M.

The vision of the MRP is to prevent melanoma initiation and progression, and reduce hardship. The mission is to support development of earlier interventions to enhance mission readiness, diminish melanoma burden, and improve quality of life for Service Members, Veterans, their Families, and the American public.

Studies involving non-melanoma skin cancers are not allowed under the FY24 MRP.

II.A.1. FY24 MRP Focus Areas

The MRP has identified three strategic priorities to ensure that funded research addresses unmet needs and/or underfunded areas of melanoma research and patient care. Those three priorities are:

Prevention and Interception: Individuals diagnosed with melanoma have significantly improved prognoses when the disease is diagnosed and treated before it has metastasized. Although primary prevention is critical, the MRP seeks to fund research that will lead to improved detection and monitoring capabilities, particularly for individuals at highest risk, as well as inhibition of melanoma initiation, early dissemination, emergence from tumor dormancy, and metastases (i.e., interception).

With the exception of studies investigating rare melanomas, the FY24 MRP is not requesting research into macrometastatic disease or treatment of macrometastatic disease.

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, and the rare melanoma sub-types are typically less-well studied. This has led to a variety of prevention, diagnosis, and treatment challenges.   The MRP seeks to fund research across the entire cancer research spectrum (i.e., biology, etiology, prevention, diagnosis and detection, prognosis, treatment, and quality of life) that addresses unmet needs and knowledge gaps associated with rare melanomas.

Survivorship: The widely accepted definition of cancer, and therefore melanoma, survivorship spans *the time from an individual receiving their initial diagnosis through the balance of their life*. *Under this definition, an individual is considered a melanoma survivor beginning at the time they receive their initial diagnosis*. For the purposes of this Focus Area, the needs and impact of a melanoma diagnosis on family members, friends, and caregivers of melanoma survivors are also included within the purview of "melanoma survivorship." With the increasing incidence of melanoma and the increased availability of effective treatment options for melanoma patients, the number of melanoma survivors is also increasing. Melanoma survivorship research, including wellness-related studies, covers a broad range of research areas that have the goal of improving the health and well-being of melanoma survivors and their families/caregivers. The MRP seeks to fund innovative and impactful research that advances studies in preservation of function (physical ability), quality of life improvement, symptom management, treatment outcomes, and support for psychological and social issues related to melanoma diagnosis, treatment, and life post-treatment.

To be considered for funding, all applications for the FY24 MRP Melanoma Academy Scholar Award must address at least one of the following FY24 MRP Focus Areas that support the MRP strategic priorities:

<u>*Prevention and Interception*</u>*:*

- Identify and understand risk factor determinants and biomarkers for melanoma.

- Develop new tools for the detection, diagnosis, and monitoring of melanoma. Studies may include, but are not limited to, developing technology, biomarkers, etc. that can distinguish between lesions and/or individuals at higher risk for progression from the lesions and/or individuals only requiring surveillance.

- Define the mechanisms of melanoma initiation, response to therapy (prior to tumor metastasis), progression, recurrence, emergence from tumor dormancy, and/or metastatic spread. Studies may include the role of the tumor microenvironment and/or microbiome in these processes.

- Develop new preclinical models that more faithfully represent disease evolution observed in humans, from melanomagenesis through progression. This includes models for either cutaneous melanoma or any of the rare melanoma subtypes.

<u>*Rare Melanomas*</u>*:*

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

<u>*Survivorship*</u>*:*

- Address the psychological and social impacts of a melanoma diagnosis, symptom trajectories, adverse effects of treatment, and other outcomes that affect melanoma survivors and their family members/caregivers.

- Address the physical impacts of symptom trajectories; acute and late-occurring adverse effects of treatment, including toxicities, reproductive and sexual health issues, and side effects that may not manifest until after treatment has ended; role of diet, exercise, and other lifestyle factors on treatment outcomes and/or quality of life; etc.

II.A.2. Award History

The MRP Melanoma Academy Scholar Award (MASA) mechanism was first offered in FY21. Since then, 20 compliant, full applications have been received, and eight have been recommended for funding. In FY23, the MRP received 14 compliant, full applications, and three were recommended for funding.

II.B. Award Information

Melanoma Academy Background:

The MRP Melanoma Academy (MA) is a unique, multi-institutional virtual academy providing intensive monitoring, national networking, collaborations, and a peer group for early-career investigators. The overarching goal of the MA is to develop a network of successful, highly productive melanoma researchers in a collaborative research and career development environment.

The MA members include Scholars and their Career Guides (primary mentors) and the MA is led by a Director and Deputy Director (i.e., the MA Leadership). The MRP Melanoma Academy Scholar (i.e., the investigator named as the Principal Investigator [PI] on the MASA application) is expected to participate in all development and training activities hosted by the MA Leadership, such as participation in monthly webinars and one-on-one mentoring sessions. Additionally, the Scholar and Career Guide are expected to communicate and form collaborations with the other members of the MA, and build relationships within the melanoma patient advocacy community.

The MA Leadership serves as a resource for the Scholars and Career Guides, assesses the progress of Scholars, and facilitates communication and collaboration among all Scholars and Career Guides, as well as with national research and patient advocacy communities. In addition to fostering scientific development, the MA Leadership provides opportunities for professional and leadership development of the Scholars, including the skills and competencies needed to fund and manage a productive laboratory. Applicants to the FY24 MASA can learn more about the MA on the MRP website.

Intent of the MASA:

The intent of the FY24 MASA is to solicit applications for Scholars to join the MA. This award mechanism enables the Scholar to pursue a melanoma project, with the guidance of a Career Guide, that may be basic, translational, and/or clinical research and addresses at least one of the FY24 MRP Focus Areas in Section II.A.1. ***The Career Guide does not have to be at the same institution as the Scholar.*** In addition to the activities described above, the Scholar and their Career Guide are required to attend a Department of Defense (DOD) MRP biennial multi-day MA workshop. In alternate years, they must also attend a DOD MRP MA 1-day workshop.

The MRP encourages MASA applications from those whose ability to commit to conducting melanoma research is limited by minimal resources or a lack of resources – such as lack of a qualified Career Guide – at their institution, access to melanoma research tools, opportunities for establishing collaborations, or other obstacles.

Key aspects of the MASA:

Principal Investigator: The PI (i.e., Scholar) must be an early-career researcher or physician-scientist *no more than 7 years from obtaining their first faculty-level appointment*. *Postdoctoral fellows (and equivalent) are not eligible for this award mechanism.* The PI's record of accomplishments and the proposed research will be evaluated regarding their potential for contributing to the FY24 MRP Focus Area(s) in Section II.A.1. Not all of the PI's accomplishments need to be in the field of melanoma. The PI's organization must demonstrate a commitment to the PI through confirmation of independent laboratory space.

Impact: The impact of the proposed research must relate to at least one of the FY24 MRP Focus Areas in Section II.A.1. Impactful research, including basic research, should expedite the advancement of promising ideas towards clinical and/or public utility. The application must articulate the short- and long-term impact the proposed research will have on *melanoma research and/or patient care*.

Career Development: A Career Development and Sustainment Plan (Attachment 7) is required and should be prepared with appropriate guidance from the Career Guide. The Career Development and Sustainment Plan should include a clearly articulated strategy for establishing collaborations and acquiring the necessary skills, competencies, and expertise to *advance and sustain an independent career at the forefront of the melanoma field*. The Scholar must show milestones and career pathways toward achieving the milestones. The Scholar must articulate commitment to interactions with the MA.

Career Guide: The Scholar must designate a Career Guide. The Career Guide must be an experienced melanoma researcher, as demonstrated by a strong record of funding and publications in melanoma. In addition, the Career Guide must demonstrate a commitment to advancing the Scholar's career in the melanoma field. *The Career Guide must also be committed to fully participating in the MA throughout the award period of performance, including interacting with other MA Scholars and Career Guides and participating in MA activities (e.g., serving on the MA Advisory Board) as requested by MA Leadership. The Career Guide must not be the named Career Guide on any previously funded (FY21-FY23) MASA applications, nor may a Career Guide be named on more than ONE FY24 MASA application.*

Preliminary Data NOT Required: Preliminary data are not required. However, any unpublished, preliminary data presented should originate from the laboratory of the PI or a member of the research team.

Other important considerations:

Melanoma Resources: When appropriate and feasible, PIs are encouraged to utilize 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 DOD, CDMRP, or MRP.

- [National Cancer Institute (NCI) Patient-Derived Models Repository (PDMR)](#). The PDMR is a national repository of patient-derived models 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 catalog currently contains numerous melanoma PDXs, PDCs, organoids, and 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.

- [U.S. 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 currently limited to ONLY VA-affiliated researchers.

- [American Association for Cancer Research Project GENIE](#). Project GENIE is a publicly accessible cancer registry of real-world clinico-genomic data assembled through data sharing between 19 international cancer centers. As of the January 2024 release there were over 198,000 sequenced samples from more than 172,000 patients, with melanoma samples (including uveal melanoma) being well-represented.

- [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.

- [INSIGHT: A Global Ocular Melanoma Patient Registry](#). The ocular melanoma INSIGHT patient registry is a collaborative effort between A Cure In Sight and University of California San Francisco Beckman Eye Center, and the National Organization for Rare Disorders to study Ocular Melanoma that began in 2019.

- [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 Military Health System is critical. Therefore, the MRP seeks to support research that is relevant to the healthcare needs of Service Members, Veterans, and/or 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.

- Applications from investigators within the military Services and applications involving multidisciplinary collaborations among academia, industry, the military Services, VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to 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.

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 4, for additional information.

A list of websites that may be useful for identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in [Appendix 2](#) of this document.

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 clinical and 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 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE 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.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers:

Clinical trials are NOT allowed under the Melanoma Academy Scholar Award.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. **Clinical research** more broadly encompasses all other research with human data, human specimens, and/or interaction with human subjects.* Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

*Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

Organizational-Level Areas of Emphasis:

The following areas of emphasis are broadly applicable to many CDMRP programs, not just the MRP. They are areas of health and medicine identified as having knowledge gaps that need to be addressed. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research, addresses the FY24 MRP strategic priorities described in Section II.A.1, and meets the intent of the MASA.

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

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

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.

Funding Details:

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 MRP Melanoma Academy Scholar Award should not exceed **$550,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $2.64M to fund approximately three Melanoma Academy Scholar Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year

of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

- **Scholar**

  To be named as the PI on the application, the Scholar:

  ○ Must be an independent investigator no more than 7 years from obtaining their first faculty-level appointment as of the full application submission deadline.

  ○ Must have an organizational commitment of independent laboratory space.

  ○ May be in a non-tenure track or tenure track position.

  ○ Must not have a concurrent career-development-like award at the time of this award.

  A Statement of Eligibility ([Attachment 9](#)) is required with the submission of the full application.

  An investigator in a mentored position (e.g., postdoctoral fellow, clinical fellow) at the time of full application submission is NOT considered an independent investigator and is NOT eligible to be named as the PI on the MASA application.

- **Career Guide**

To be named as the Career Guide on the application, the Career Guide:

- ○ Must be an independent, established melanoma researcher at or above the level of Associate Professor (or equivalent).

- ○ Must have melanoma research funding (past and present).

- ○ Must have a record of melanoma publications in peer-reviewed journals.

- ○ Must demonstrate a commitment to develop and sustain the Scholar's independent career in the field of melanoma.

- ○ Must be committed to fully participating in MA activities as requested by the Scholar and MA Leadership throughout the MASA period of performance.

- ○ *Must not* be the current Director or the Deputy Director of the MA. The current MA Leadership can be found here: https://cdmrp.health.mil/mrp/research_highlights/22Davies_Fisher_Holder_Chua_highlight

- ○ *Must not* be the named Career Guide on any previously funded (FY21-FY23) MASA applications.

- ○ *Must not* be named on more than ONE (1) FY24 MASA application.

Note: The Scholar and Career Guide DO NOT need to be located at the same organization.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or

Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow
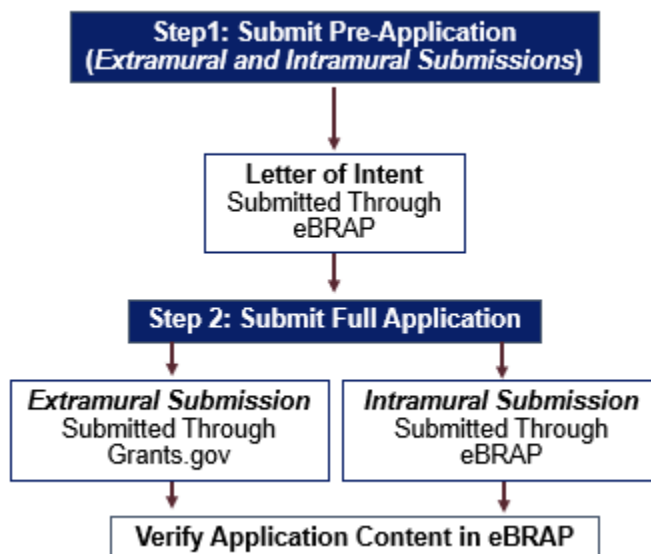
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524MRPMASA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for

HT942524MRPMASA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 MRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

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

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY24 MRP Focus Area(s) (listed in Section II.A.1) under which the full 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. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

II.D.2.b. Step 2: Full Application Submission

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)***:** Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- ○ **Attachment 1: Project Narrative (eight-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  - – **Background:** Present the scientific rationale to support the proposed research project and its feasibility, as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. ***Preliminary data are not required.*** Any unpublished preliminary data presented should originate from the laboratory of the PI or a member of the research team.

  - – **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 proposed research is part of a larger study, ***present only tasks that this award would fund.***

  - – **Research Strategy and Feasibility:** Describe the experimental design, methodology, and analyses, including appropriate controls, in sufficient detail for evaluation. Describe how the studies are designed to achieve the project aims. Address potential problem areas and present alternative methods and approaches.

    - ▪ Clearly describe the statistical plan and the rationale for the statistical methodology. If applicable, describe an appropriate power analysis, how it supports the sample size, and how it adequately represents an assessment of the population or subpopulation proposed. If there are sample size limitations (e.g., because of budget limitations) justify how results from the proposed sample size(s) will yield meaningful information.

    - ▪ 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/were 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 participants 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 participants, and for acquiring any additional research resources necessary for conducting the proposed research project. If there are sample size limitations justify how the proposed sample size(s) will provide sufficient information to support moving forward with the line of research.

- 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 Institutional Review Board [IRB] review) are exempt from this requirement. ***This award cannot be used to conduct clinical trials.*** See Attachment 2 for instructions regarding the Inclusion Enrollment Report that is required with all applications that propose clinical research.

- If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.

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

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

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

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

Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional

facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

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

Letters of Organizational Support (two-page limit per letter *is recommended*): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources (e.g., start-up package) available for the Scholar/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)* **(two-page limit per letter *is recommended*):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

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

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

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

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

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

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

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

Inclusion Enrollment Plan *(only required if clinical research is proposed)***:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be 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.

- ○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  The technical abstract should be written using the outline below. Clarity and completeness within the space limits are highly important.

– **Background:** Present the scientific rationale behind the proposed project.

– **Hypothesis/Objective:** State the hypothesis to be tested/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:** Summarize how the proposed project will make an important contribution toward at least one of the FY24 MRP Focus Areas described in Section II.A.1.

The abstract may include a header identifying the name of the attachment (e.g., "Technical Abstract") to aid the review of the application, as long as the page limit is not exceeded.

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

The lay abstract should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine*. Avoid overuse of scientific jargon, acronyms, and abbreviations.

– State the FY24 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 project.

– Summarize the Scholar's career goals in melanoma research. How will the proposed research, participation in the MRP MA, and the Career Development and Sustainment Plan support the Scholar in attaining these goals? Explain the Scholar's potential as a leader in the melanoma field.

– Describe the applicability of the research to melanoma patients and/or survivors by considering the following points:

  ▪ What types of patients will the proposed research help and how will it help them?

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

  ▪ Describe the short- and long-term goals that are related to patient care, outcomes, or survivorship. If the research is too basic for short-term clinical applicability, describe the interim research outcomes expected and their applicability to the

field of melanoma. Basic research should have the long-term goal of advancing the melanoma field and/or impacting patient care.

- ▪ How will the proposed research benefit Service Members, Veterans, their Families, and the American public?

The abstract may include a header identifying the name of the attachment (e.g., "Lay Abstract") to aid the review of the application, as long as the page limit is not exceeded.

- ○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the "Suggested SOW format" to develop the SOW for the proposed research. For the MASA, refer to the "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW.

- ○ **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 work uniquely addresses a critical problem in at least one of the FY24 MRP Focus Areas in Section II.A.1. Explain how the anticipated research outcome(s) and/or product(s) resulting from the research project will advance the melanoma field and/or impact patient care in the short term. Describe the long-term vision for how the Scholar's specific career and research goals, if accomplished, will impact the lives of melanoma patients and/or survivors. Describe the relevance of the proposed research to the health and well-being of Service Members, Veterans, their Families, and all people affected by melanoma. *All research, including basic, should relate to patient outcomes and how it benefits those affected by melanoma.*

The statement may include a header identifying the name of the attachment (e.g., "Impact Statement") to aid the review of the application, as long as the page limit is not exceeded.

- ○ **Attachment 7: Career Development and Sustainment Plan (two-page limit): Upload as "CareerSustain.pdf".**

  - – Discuss the Scholar's record of accomplishments (awards, honors, first and/or corresponding author publications, publications in high-impact journals, presentations/speaking engagements, committees, etc.) demonstrating the potential for becoming an established investigator at the forefront of the melanoma field.

  - – Describe the Scholar's motivation and commitment to participating in the MA, including networking and collaborating with the other Scholar/Career Guide pairs and the MA Leadership.

  - – Describe the individualized career and professional development plan, which may include classes, workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Include milestones to be achieved during the award period of performance and pathways toward achieving the milestones. Explain how this development plan will enable the Scholar to obtain independent melanoma research funding and publish in peer-reviewed journals.

- Explain how the Career Development and Sustainment Plan is supported by the environment. This should include a description of resources available to the Scholar at their institution, and, if different, at the Career Guide's institution. If the Scholar is impacted by resource limitations at their institution, explain how participation in the MA will overcome these obstacles.

- Discuss how the Career Guide will assist the Scholar in not only developing, but also sustaining, a career as an independent melanoma researcher.

- Outline how the Scholar and Career Guide, together, will evaluate the Scholar's progress of achieving and sustaining a productive and independent career in melanoma research.

The first page of the plan may include a header identifying the name of the attachment (e.g., "Career Development and Sustainment Plan") to aid the review of the application, as long as the page limit is not exceeded.

○ **Attachment 8: Career Guide's Letter (two-page limit): Upload as "GuideLetter.pdf".**

The Career Guide's letter should:

- Describe the Scholar's background and potential to become an established melanoma researcher.

- Summarize the Career Guide's background and experience in the field of melanoma, success in acquiring funding in melanoma research, publication record in melanoma, and record of mentoring and training early-career investigators. This information should be substantiated by details provided in the Career Guide's biographical sketch and previous/current/pending support documentation.

- Describe the specific resources that the Career Guide has/had access to that will facilitate success for the Scholar.

- Specify the commitment of the Career Guide and their staff to the Scholar's professional development and career sustainment. If the Career Guide and Scholar are located at different organizations, describe how appropriate direction and oversight will be accomplished.

- Describe the Career Guide's motivation and commitment to participating in the MA throughout the MASA period of performance.

○ **Attachment 9: Statement of Eligibility (one-page limit): Upload as "Eligible.pdf".** Provide a letter signed by the PI (the Scholar) and the Department Chair, Dean, or equivalent organization official to verify that the eligibility requirements have been met. The letter should verify that the PI is *no more than 7 years from their first faculty-level appointment* and include the organizational commitment for independent laboratory space. (Refer to Section II.C, Eligibility Information.)

- ○ **Attachment 10: Representations** *(Extramural Submissions Only)***: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- ○ **Attachment 11: Suggested Intragovernmental/Intramural Budget Form** *(if applicable)***: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

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

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

- ○ **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- ○ **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- ○ **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

  Include Career Guide's biographical sketch.

- ○ **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

  Include Career Guide's previous/current/pending support.

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

- ○ **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural

submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)***:** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- o **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$550,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

- Travel costs for the Scholar and Career Guide to attend a DOD MRP 1-day Melanoma Academy Workshop with the MA Leadership and other MA members every other year.

- Travel costs for the Scholar and Career Guide to attend a biennial DOD MRP multi-day Melanoma Academy Workshop with the MRP staff, MA Leadership, and other Academy members.

For planning purposes, it can be assumed that the MA Workshops will be located in either Boston, MA or Houston, TX. The specific dates and locations will be determined during the period of performance.

May be requested for (not all-inclusive):

- Maximum allowable funding for the Career Guide(s) is $30,000 per year in direct costs.

- Travel costs in support of collaborative research.

- Costs associated with participating in the MA (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications).

- Costs for one investigator to travel to two scientific/technical meetings per year in addition to the required MA meetings/workshops described above. The intent of travel costs to scientific/technical meetings should be to present project information or disseminate project results and/or attend workshops as designated in the Career Development and Sustainment Plan (<u>Attachment 7</u>) of the MRP MASA application.

Must not be requested for:

- Tuition of graduate students

- Clinical trial costs

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **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, relevant preliminary data *(if included; preliminary data not required)*, and logical reasoning.

    ○ To what extent the hypothesis or objective, research strategy, methods, and analyses are developed and support successful completion of the specific aims.

    ○ How well the application acknowledges potential problem areas and presents alternative methods and approaches.

    ○ To what extent the scope of the proposed research is appropriate for the allowed budget and period of performance limits.

    ○ 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 application demonstrates the availability of human data sets, human anatomical substances, and/or human participants, including a detailed plan for the acquisition of samples/resources and/or recruitment of human participants 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. Whether a completed Inclusion Enrollment Report providing anticipated enrollment table(s) for the inclusion of women and minorities is included with the application.

- **Impact**

  ○ To what extent the proposed research uniquely addresses a critical problem in at least one of the FY24 MRP Focus Areas in Section II.A.1.

  Assuming the objectives/aims of the proposed research are realized, to what degree:

  ○ The anticipated research outcomes and/or product(s) resulting from the research project will advance the melanoma field and/or impact patient care in the short term.

  ○ The long-term vision for how the Scholar's specific career and research goals, if accomplished, will impact the lives of melanoma patients and/or survivors.

  ○ The proposed research is relevant to the health and well-being of Service Members, Veterans, their Families, and all people affected by melanoma.

- **Scholar**

  ○ To what extent the Scholar's record of accomplishments demonstrates their potential for becoming an established investigator at the forefront of the melanoma field.

  ○ To what extent the application describes the Scholar's motivation and commitment to participating in the MA, to include networking and collaborating with the other Scholar/ Career Guide pairs and the MA Leadership.

  ○ How well the Career Guide's letter describes the Scholar's background and supports the potential of Scholar to become established in the melanoma field.

- **Career Development and Sustainment Plan**

  ○ To what extent the individualized Career Development and Sustainment Plan will enable the Scholar to obtain independent melanoma research funding and publish in peer-reviewed journals.

  ○ Whether milestones and career pathways toward the milestones are included and achievable within the allotted period of performance.

  ○ How well the Career Development and Sustainment Plan is supported by the environment, including a description of resources available to the Scholar at their institution, and, if different, at the Career Guide's institution.

  ○ If applicable, to what extent the Scholar explains how participation in the MA will overcome resource limitations at their institution.

  ○ To what extent the Career Guide and their staff will assist the Scholar in not only developing, but also sustaining, a career as an independent melanoma researcher.

- **Career Guide**

  - To what extent the Career Guide's background and experience in the field of melanoma, success in acquiring funding in melanoma research, publication record in melanoma, and record of mentoring and training early-career investigators are appropriate for their role in the MA.

  - To what degree the Career Guide is motivated and committed to participating in the MA.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Personnel**

  - If applicable, to what degree the background and expertise of the research team based on biographical sketches (other than the Scholar and Career Guide) are appropriate to accomplish the proposed research.

- **Data and Resource Sharing**

  - To what extent the plan for sharing project data and research resources is appropriate and reasonable.

  - If applicable, whether the specific repository(ies) are named where scientific data and/or resources arising from the project will be archived.

- **Budget**

  - Whether the direct costs exceed the allowable direct costs as published in the program announcement.

- **Environment**

  - Whether there is clear commitment from the institution (at least 50% protected time for melanoma research) that supports the career development of the Scholar, including time for participating in MA activities, as directed by MA Leadership.

  - 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 priorities of the Defense Health Program and FY24 MRP, as evidenced by the following:

  ○ Relevance to at least one of the FY24 MRP Focus Areas in Section II.A.1

  ○ Adherence to the intent of the MASA described in Section II.B

  ○ Relative impact

  ○ Relative career potential of the Scholar in the melanoma field

  ○ Program portfolio balance

  ○ Relevance to military health

II.E.2. Application Review and Selection Process

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

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

of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the MRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of

funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

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

PHS Inclusion Enrollment Reporting Requirement (**Required for clinical research**): 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 SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

>   Phone: 301-682-5507

>   Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

>   Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

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

- An FY24 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, including letters of support/recommendation. *A list of the FY24 MRP Programmatic Panel members can be found at https://cdmrp.health.mil/mrp/panels/panels24.*

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The application does not address at least one of the FY24 MRP Focus Areas in Section II.A.I.

- The PI (i.e., Scholar) does not meet the eligibility criteria.

- The named Career Guide does not meet the eligibility criteria.

- A clinical trial is proposed.

- 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. Full Application Submission Checklist

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

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting *In Vivo* 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
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
HCMI	Human Cancer Models Initiative
IRB	Institutional Review Board
M	Million
MA	Melanoma Academy
MASA	Melanoma Academy Scholar Award
MB	Megabytes
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
MVP	Million Veteran Program
NCI	National Cancer Institute
OM	Ocular Melanoma
PDC	Patient-Derived Tumor Cell Cultures
PDF	Portable Document Format
PDMR	Patient-Derived Models Repository
PDX	Patient-Derived Xenograft
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command

USC	United States Code
VA	U.S. Department of Veterans Affairs
VA SHIELD	VA Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases

APPENDIX 2: DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DOD and/or VA research laboratories and programs. Collaboration with DOD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DOD and VA areas of research interest, ongoing research, or potential opportunities for collaboration.

Air Force Office of Scientific Research
https://www.afrl.af.mil/AFOSR/

Air Force Research Laboratory
https://www.afrl.af.mil/

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://cccrp.health.mil/Pages/default.aspx

Congressionally Directed Medical Research Programs
https://cdmrp.health.mil/

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Health Agency
https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/

Defense Suicide Prevention Office
https://www.dspo.mil/

Defense Technical Information Center
https://www.dtic.mil/

Defense Threat Reduction Agency
https://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.health.mil/sitepages/home.aspx

Military Infectious Diseases Research Program
https://midrp.health.mil/

Military Operational Medicine Research Program
https://momrp.health.mil/

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Command/R-D-Commands/Naval-Health-Research-Center/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-and-Marine-Corps-Force-Health-Protection-Command/

Naval Medical Research Command
https://www.med.navy.mil/Naval-Medical-Research-Command/

Office of Naval Research
https://www.nre.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
https://www.acq.osd.mil/

Telemedicine and Advanced Technology Research Center
https://www.tatrc.org/

Uniformed Services University of the Health Sciences
https://www.usuhs.edu

U.S. Army Aeromedical Research Laboratory
https://usaarl.health.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/devcom

U.S. Army Institute of Surgical Research
https://usaisr.health.mil/

U.S. Army Medical Materiel Development
Activity
https://usammda.health.mil/

U.S. Army Medical Research and
Development Command
https://mrdc.health.mil/

U.S. Army Medical Research Institute of
Infectious Diseases
https://usamriid.health.mil/

U.S. Army Research Institute of
Environmental Medicine
https://usariem.health.mil/

U.S. Army Research Laboratory
https://www.arl.army.mil/

U.S. Army Sharp, Ready and Resilient
Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury
Research Program
https://blastinjuryresearch.health.mil/

U.S. Department of Veterans Affairs, Office
of Research and Development
https://www.research.va.gov/

U.S. Naval Research Laboratory
https://www.nrl.navy.mil/

Walter Reed Army Institute of Research
https://wrair.health.mil/