

Program Announcement for the Department of Defense Defense Health Program

Melanoma Research Program Melanoma Academy Leadership Award

Funding Opportunity Number: HT942525MRPMALA

Pre-Application Due: September 10, 2025

Application Due: October 1, 2025

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Before You Begin

- Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission. User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- Read the funding opportunity announcement in the order it is written before beginning to prepare application materials. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.
- Refer to the FY25 CDMRP <u>Frequently Asked Questions</u> document for answers to common inquiries regarding the funding opportunity announcements and application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507 help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726 International: 1-606-545-5035 support@grants.gov

> Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

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1. Basic Information About the Funding Opportunity

Summary: This funding opportunity announcement seeks to solicit *a Director and Deputy Director to lead* the Melanoma Research Program (MRP) Melanoma Academy. The Melanoma Academy is a unique, interactive virtual academy focused on bringing together established investigators and independent, early-career investigators (Scholars) to develop successful, highly productive melanoma researchers in a collaborative research and career development environment.

Distinctive Features: This funding mechanism is a *partnering* mechanism, requiring an Initiating Principal Investigator (PI) who will serve as the Melanoma Academy Director and a Partnering PI who will serve as the Melanoma Academy Deputy Director.

• Only the Initiating PI will submit a pre-application. Both PIs will need to submit full applications; the Partnering PI's application is an abbreviated package. If recommended for funding, each PI will be named on separate awards to the recipient organization(s).

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.82 million (M) to fund approximately one Melanoma Academy Leadership Award application with combined total cost cap of \$1.82M. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), September 10, 2025
- Application Submission Deadline: 11:59 p.m. ET, October 1, 2025
- End of Application Verification Period: 5:00 p.m. ET, October 7, 2025
- Peer Review: December 2025
- Programmatic Review: February 2026

Announcement Type: Modified

Funding Opportunity Number: HT942525MRPMALA

Assistance Listing Number: 12.420

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2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply, *including foreign and domestic organizations*, *for-profit and non-profit organizations*, *and public or private entities*.

Extramural Organization: An eligible non-Department of Defense (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.

2.1.2. Principal Investigator

Academy Director and Deputy Director:

- 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.
- The Director and the Deputy Director must not be named as a Career Guide on any FY25 Melanoma Academy Scholar Award applications.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

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

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3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the MRP. 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 \$180M. The FY25 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 FY25 MRP.

3.1. Award History

The MRP Melanoma Academy Leadership Award mechanism was previously offered in FY21. Two Melanoma Academy Leadership Award applications representing four potential awards were received, and one application representing two awards was recommended for funding.

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 initiated in FY21. 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 to advance the melanoma field and improve the health and well-being of everyone impacted by melanoma.

The MRP-funded MA members currently include eight Scholars (i.e., independent, early career investigators) from different institutions and their Career Guides (primary mentors) and a Director and Deputy Director (i.e., the MA Leadership). Additionally, from FY20-FY23 the MRP funded 14 Mid-Career Accelerator Awards, the PIs of which have the option of participating in MA activities such as monthly webinars and annual workshops. Information about the FY21 MA Leadership and Scholar Awards, the FY22 Cohort of Scholars, and a high-level overview of the MA from FY21-FY23 is available on the MRP webpages.

3.2. Intent of the Melanoma Academy Leadership Award

The FY25 Melanoma Academy Leadership Award (MALA) mechanism is soliciting applications for a Director and Deputy Director to continue the MA and lead the effort towards achieving its overarching goal. The MA Director and Deputy Director (referred to as MA Leadership) must be established melanoma researchers and should be at different institutions. The MA Leadership must demonstrate a strong record of mentoring and training early-career independent investigators, a commitment to leadership and establishing and sustaining research collaborations, and the ability to objectively assess the progress of all Scholars in the MA.

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The MA Leadership facilitates collaboration and communication among all Scholars and Career Guides as well as with national research and patient advocacy communities, and fosters connections between Scholars and other national and international melanoma experts who may not be directly affiliated with the MA (Figure 1). The intention is that through the MA, collaborations will foster new growth and research advancements toward better understanding of melanoma prevention and interception, rare melanomas, and melanoma survivorship. In collaboration with a Scholar's designated Career Guide, 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.

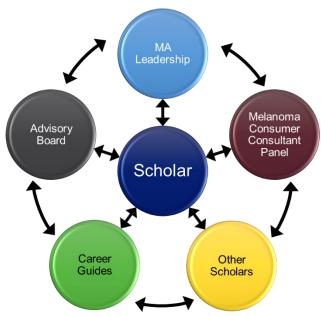


Figure 1: Infographic demonstrating the intended collaborative environment provided for Scholars as part of the MRP Melanoma Academy. Scholars should benefit from not just the Academy Leadership, but also the breadth of experience, resources, and expertise of the Advisory Board, the Melanoma Consumer Consultant Panel, and other Scholars and Career Guides.

The MA should foster convergent science wherein investigators from different disciplines solve specific problems together and take a cross-disciplinary approach to accelerate moving the melanoma field forward. The MA should give Scholars opportunities to operate within a collegial, highly dynamic, and cutting-edge environment to lead melanoma research and patient care to a new frontier.

The Melanoma Academy Leadership Award is structured to support two Pls. The MA Director will be identified as the Initiating Pl and will be responsible for the majority of the administrative tasks associated with application submission. The Deputy Director will be identified as the Partnering Pl. The collaboration between the Academy Director and the Deputy Director should be supported by complementary expertise and experience. Both Pls should contribute significantly to the development and execution of the proposed MA organization and administration. If recommended for funding, each Pl will be named on separate awards to the recipient organization(s); the newly selected Director and Deputy Director will initiate their responsibilities no later than 30 September 2026. Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering Pl, refer to Section 5.3, Submission Instructions.

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The application should clearly demonstrate that both PIs have significant levels of input on the proposed MA Leadership and clearly define the components to be addressed by each to continue the success of Scholars. While it is up to the Academy Director and the Deputy Director to define their roles, both MA Leaders should have interactions with the Scholars; acting as administrative support does not fulfill the intent of the Deputy Director. If recommended for funding, each PI will be named to an individual award within the recipient organization.

Independent, early career investigators interested in applying to become a member of the MA should refer to the FY25 Melanoma Academy Scholar Award funding opportunity announcement (HT942525MRPMASA).

3.2.1. Focus Areas for the MALA

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 (use of sunscreen, sun avoidance, etc.) 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 FY25 MRP is not requesting research into macrometastatic disease or treatment of macrometastatic disease.

Rare Melanomas: Rare melanoma subtypes can have distinct characteristics compared to cutaneous melanoma, which makes up the majority of melanoma diagnoses. Rare melanoma subtypes are typically less well-studied, and 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. Although the FY25 MRP will accept applications addressing topics relevant to uveal melanoma, the MRP is particularly interested in receiving applications that address other uncommon presentations of melanoma, including but not limited to:

- Genetic (molecular subtypes).
- Histologic (desmoplastic and acral lentiginous).
- Tissue of origin (mucosal, acral).
- Clinical presentation (pediatric, leptomeningeal disease).

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 patients with melanoma, the number of melanoma survivors is also increasing. Melanoma survivorship research covers a broad range of research areas that

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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.

The MA vision and goals described in the MALA application should be complementary to the following FY25 MRP focus areas that support the MRP strategic priorities:

Prevention and Interception:

- 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 and/or resistance to adjuvant and/or neoadjuvant therapy, 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.

Rare Melanomas:

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

Survivorship:

- 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.

3.2.2. Responsibilities of the Academy Leadership

The list below is not meant to be exhaustive, but rather highlight several considerations that the MA Leadership should incorporate into the planning and execution of MA activities.

- Set the vision and mission of the MA, including how the MA Leadership will integrate different disciplines into one cohesive unit.
- Act as a resource for all Scholars and Career Guides in the Academy over the 4-year period of performance.
- Facilitate communication and collaboration among all Scholars and Career Guides, including periodic interactive communication among all Academy members and developing ideas for future collaborative research projects.

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- Plan and host an annual one-day workshop and biennially, a multi-day workshop for all Scholars/Career Guide pairs as well as Academy graduates to present their research, share knowledge, and develop collaborative efforts within the MA.
- Provide avenues to increase the visibility of Scholars within melanoma research and advocacy communities (e.g., peer review, conferences, editorial boards).
- Support the professional development of Scholars (e.g., lab management skills) through invited presentations from experts outside the MA..
- Develop an evaluation plan to assess the research progress made by all Scholars, as well as their career progression and sustainment as independent investigators in melanoma research and/or patient care.
- Develop an evaluation plan to assess the MA's progress toward meeting its vision and mission.
- Establish a Melanoma Consumer Consultant Panel, consisting of at least two melanoma
 consumer consultants, to inform the MA on the needs of the melanoma community and
 include them in MA activities (meetings, workshops, etc.). The Melanoma Consumer
 Consultants may be representatives from community-based organizations or advocacy
 groups, melanoma survivors (active or post-treatment), their family members, or caregivers.
 To maximize the relevance of the MA to military health, at least one of the Melanoma
 Consumer Consultants is expected be a Service Member or Veteran.
- Establish an Advisory Board that incorporates experts in the field, Career Guides, MA Alumni (as appropriate), and at least one Melanoma Consumer Consultant from the Melanoma Consumer Consultant Panel.

3.2.3. Other Important Considerations for the MALA

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 health care needs of Service Members, Veterans, and/or their Families. Pls 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, U.S.
 Department of Veterans Affairs (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 the <u>full application submission components</u>, for detailed information. Refer to the General Application Instructions, Appendix 4, for additional information.

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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 3 of this document.

Clinical trials are NOT allowed under the Melanoma Academy Leadership 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. An **intervention** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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 encompasses 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.

3.3. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the MRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

- Innovative research involving nuclear medicine and related techniques to support early
 diagnosis, more effective treatment, and improved health outcomes of 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.
- The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

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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 and submit research
ideas to address these recommendations provided they are within the limitations of this
funding opportunity and fit within the FY25 MRP Strategic Priorities.

3.4. Funding Instrument

The funding instrument for awards made under the program announcement will be cooperative agreements (31 USC 6305). Substantial CDMRP programmatic involvement with recipients is anticipated during the performance of award activities. Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to providing input regarding content and quality of MA activities such as monthly webinars, annual workshops, execution of pilot projects, etc.

3.5. Funding Details

Period of Performance: The maximum period of performance is **4** years.

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **\$1,820,000**. 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 **4** years.

The appropriateness of the budget for the proposed research will be assessed during peer review.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in leading the MA, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Direct Cost Restrictions: For this award mechanism, direct costs:

Must be requested for:

- Costs associated with planning and hosting the annual one-day workshop with MA members, including costs associated with external speakers.
- Costs associated with planning and hosting the biennial multi-day workshop in coordination with the MRP Program staff, including costs associated with external speakers.
- Travel costs associated with attending a Milestone meeting as described in Section 8.3.

May be requested for (not all-inclusive):

- Costs associated with establishing and maintaining a "virtual" academy (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications).
- Support for multi-institutional collaborations, including travel.

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Travel costs for MA Leadership to attend MA workshops.

Must not be requested for:

- Any travel costs for the Melanoma Academy Scholar Awardees or their Career Guides; their travel costs will be covered by their respective Melanoma Academy Scholar Awards.
- Tuition of graduate students.
- Clinical trial costs.

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4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (<u>eBRAP</u>) and a *full application* submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

Letter of Intent (LOI) (one-page limit): Provide a brief description of the proposed MA.

4.3. Step 2: Full Application Components

The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

4.3.1. Full Application Components for the Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

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

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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 (20-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.

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- Vision: Describe the MA Leadership's (Director and Deputy Director) vision of the MA and how it will serve as a non-traditional, non-conventional career and scientific development platform, including intensive mentoring and networking for the Scholars in a virtual environment. Describe the mission and roadmap as to how the MA will develop highly productive melanoma researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 4-year period of performance. Articulate the overall goals of the MA with respect to the FY25 MRP focus areas.
- Background and Experience: Describe the MA Leadership's background and experience as established melanoma researchers and/or clinicians. Describe the record of mentoring and training of early-career investigators and how this mentorship contributed significantly to the early investigators' careers. Explain how the complementary experience of both candidates contributes to the ideal leadership of the Academy.
- Commitment to the Melanoma Academy: Describe the Academy Leadership's commitment to leading the MA, and to the success of this unique, interactive virtual academy in providing collaborative mentoring of Scholars with the goal of developing sustainable, independent careers as leaders in the melanoma field at their institutions, nationally, and internationally.
- Management of the Academy: Clearly define the roles that will be filled by the Academy Director and Deputy Director in leading the MA. Describe how the Academy Leadership will avoid "stovepiping" (i.e., a system where information is transmitted through narrow channels) and will catalyze cross-disciplinary communication and collaboration among all of the Scholars and their Career Guides, the melanoma consumer community and the broader melanoma research and patient care communities (including but not limited to periodic virtual interactive meetings and annual and biennial in-person workshops). Include plans for developing externally funded collaborative research projects conducted by members of the MA (e.g., between MA Leadership and Scholar, Scholar/Scholar. Scholar/Career Guide) with input from the Melanoma Consumer Consultant Panel. Explain the opportunities provided within the MA for the Scholars overcome barriers associated with initiating and sustaining a career in melanoma research (grant writing, research and laboratory management, publications, professional networking, and committee memberships, etc.). Describe plans for including Mid-Career Accelerator Award investigators and MA Scholar Alumni in the MA.
- Scholar Evaluation Plan: Explain how the MA Leadership will evaluate the research progress made by the Scholars, their career progression, and sustainment as independent investigators in melanoma research and/or patient care. Identify measurable outcomes for the Scholars that are expected to be achieved by the end of their Melanoma Academy Scholar Award period of performance. The Scholar evaluation plan should clearly articulate:
 - What are the evaluation questions/criteria?
 - What data will be collected to answer the evaluation questions/assess the defined criteria? How will the date be collected? At what frequency? Who will collect the data? How will the data be managed and stored? If available, copies of any questionnaires, forms, etc., that may be used for data collection can be included in <u>Attachment 2</u>.

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- Who will analyze and interpret the data?
- How and when will the results be disseminated and to what audience(s) (e.g., the Scholars)? How will the MA Leadership use the evaluation findings?
- MA Evaluation Plan: Explain how the MA Leadership will evaluate the MA's progress towards accomplishing the outlined vision and mission of the Academy. Define the metrics that will be used to monitor progress, identify areas for improvement, and make informed decisions about future MA activities. The MA evaluation plan should clearly articulate:
 - What are the evaluation questions/metrics?
 - What data will be collected to answer the evaluation questions? How will the data be collected? At what frequency? Who will collect the data? How will the data be managed and stored? How will the data be managed and stored? If available, copies of any questionnaires, forms, etc. that may be used for data collection can be included in Attachment 2.
 - Who will analyze and interpret the data?
 - How and when will the results be disseminated and to what audience(s)? How will the MA Leadership use the evaluation findings?
- 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 Support (two-page limit per letter is recommended): Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PIs have the support and resources necessary for the proposed effort. Letters from the PIs' Department Chairs, or appropriate organization

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official, should also confirm that the PIs meet <u>eligibility criteria</u>. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.

- Data and Research Resources Sharing Plan: Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial 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 & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- Scholar and MA Evaluation Tools, if applicable: Pls may provide a copy of any questionnaires, forms, etc. that may be utilized to conduct the proposed Scholar and/or MA evaluations. ONLY the blank documents should be provided in Attachment 2; draft versions are acceptable. Any description of how the tools will be used in the conduct of the evaluations must be described in the project narrative. Any descriptive text that appears to extend the project narrative may be removed before the application is reviewed.
- 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.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- Describe the planning and execution of the MA. Include the following information:
 - Summarize the vision for successfully continuing the Melanoma Academy as a non-traditional, non-conventional career and scientific development platform in which the Scholars will develop into highly productive investigators poised to lead melanoma research and patient care to a new frontier.
 - Outline how the MA Leadership will catalyze cross-disciplinary communication and collaboration among all the Scholars and their Career Guides, the melanoma consumer community, and the broader melanoma research and patient care communities.
 - Describe the contributions of the Advisory Board.
- Describe how the MA Leadership will evaluate the Scholars' and Academy's progress towards achieving the stated goals.
 - Summarize the Scholar Evaluation Plan.
 - Summarize the MA Evaluation Plan.

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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.

Lay abstracts should address the points outlined below. Avoid overuse of scientific jargon, acronyms, and abbreviations.

- In a manner that will be readily understood by readers without a background in science or medicine, explain the vision and mission of the Melanoma Academy as a non-traditional, non-conventional career and scientific development platform in which the Scholars will develop partnerships, collaborations, and professional networks to ensure their dedication and productivity as leading melanoma researchers. Explain how the MA provides resources and opportunities that the Scholars may not otherwise have access to if they were not a part of the Academy.
- Describe the integration of Melanoma Consumer Consultant Panel into MA administration and execution.
- Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Refer to eBRAP for the "Suggested SOW Format".
 - For the MALA refer to the <u>"Example: Assembling a Generic Statement of Work"</u>, for guidance on preparing the SOW.
 - Include specific milestones for conducting and reporting on Scholar and MA evaluation plans.
 - Include the planning and execution for annual and biennial MA workshops.
 - Include a task for the Milestone Meeting during year 3 of the period of performance.
 - Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.
- Attachment 6: Melanoma Consumer Consultation Plan: Upload as "MCCplan.pdf".
 - Statement (two-page limit is recommended): Include the names of at least two melanoma consumer consultants; at least one consultant is expected to be a Service Member or Veteran. Describe the Melanoma Consumer Consultant Panel. Articulate the melanoma consumers' and Veteran(s)' roles on the panel and how they will be integral to the training, networking, and collaboration of the Scholars. Indicate the input that will be captured from the Melanoma Consumer Consultant Panel and how this input will be meaningfully integrated and incorporated into the workings of the MA. Explain how data and resources generated during the performance of the MA be shared with the relevant communities (i.e., scientific and advocacy organizations and the public).
 - Letters of Collaboration (two-page limit per letter is recommended): Provide a letter signed by each Melanoma Consumer Consultant confirming their role and commitment to participate on the MA Melanoma Consumer Consultant Panel. Each letter should include the individual's qualifications/background and the relevance of these qualifications to the Consultant's role on the Panel.

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- Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf". This
 attachment should be written with a broad audience in mind, including readers without a
 background in science or medicine
 - Describe how the MA will foster convergent science wherein investigators from different disciplines solve specific problems together and take a cross-disciplinary approach to accelerate moving the melanoma field forward. Indicate how the MA will synergize collaboration and foster better understanding of melanoma prevention and interception, rare melanomas, and melanoma survivorship through the multidisciplinary training and support of future leaders in the field of melanoma. Explain how the MA will incorporate military health relevance into the vision and mission of the Academy. Justify the anticipated short-term and long-term impact of the MA on melanoma research, patient care, and/or quality of life to the benefit of Service Members, Veterans, their Families, and the American public.
- Attachment 8: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf". All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- Attachment 9: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf". If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.
- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
 - Biographical Sketch: Upload as "Biosketch LastName.pdf".
 - The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.
 - Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).
 - Current/Pending Support: Upload as "Support LastName.pdf".
 - Current and pending (other) support information are used to assess the capacity or any <u>conflicts of commitment</u> that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

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Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
 - Budget Justification (no page limit): For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
 - Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to <u>Section 3.5, Funding Details</u>, for detailed information.
- (f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
 - Intramural DOD Subaward: Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

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

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf". Each PI must submit an identical copy of a jointly created SOW.

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- Attachment 8: Representations (Grants.gov submissions only): Upload as "RequiredReps.pdf".
- Attachment 9: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".
- (c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).
- (d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.
- (e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf".
 - Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.
- **(f) Project/Performance Site Location(s) Form:** For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Grants.gov Submissions Only): Refer to the General Application Instructions, Section IV.C.(e), for detailed information.
 - Extramural Subaward: Complete the Research & Related Subaward Budget Form through Grants.gov.
 - o **Intramural DOD Subaward:** Complete the "<u>Suggested Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov.

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

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5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525MRPMALA from <u>Grants.gov</u> or <u>eBRAP</u>, depending on which submission portal will be used.

5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), <u>SAM.gov</u>, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Step1: Submit Pre-Application Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Grants.gov Extramural Organizations Verify Application Content in eBRAP

Application Submission Workflow

5.3.1. Pre-Application Submission

All pre-application components must be submitted by the Initiating PI through <u>eBRAP</u>, including the submission of contact information for the Partnering PI.

NOTE: The individuals serving on the Melanoma Consumer Consultant Panel should be named during the pre-application submission. For administrative purposes, select "Consumer" when assigning the melanoma consumer consultant(s)'s roles in eBRAP under "Collaborators and Key Personnel.

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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 preapplication 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.

After the Initiating PI (i.e., MA Director) confirms submission of the pre-application, the Partnering PI (i.e., MA Deputy Director) will be notified of the pre-application submission via an email from eBRAP. The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information. If not previously registered, the Partnering PI must register in eBRAP.

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. 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 the 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*

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Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal 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.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in 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.*

All submission dates and times are indicated in <u>Section 1</u>, <u>Basic Information</u> above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the <u>CDMRP's full position on research duplication</u>.

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.

Members of the FY25 MRP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members *may* provide letters to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). A list of the FY25 MRP Programmatic Panel members can be found on the CDMRP website.

Additional restrictions and associated administrative responses are outlined in <u>Section 9.2, Administrative Actions</u>.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

6.2.2. Peer Review Criteria

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

Vision

- To what extent the vision of the MA supports the idea to serve as a non-traditional, nonconventional career and scientific development platform, including intensive mentoring and networking for the Scholars in a virtual environment.
- To what extent the mission and roadmap as to how the Academy will develop highly productive melanoma researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 4-year period of performance is described and feasible.
- Whether the overall goals of the MA with respect to the <u>FY25 MRP focus areas</u> are described.

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Academy Leadership

- To what extent the Academy Director's and Deputy Director's background and experience in melanoma research demonstrate their potential for leadership of the MA.
- To what extent the Academy Leadership's record of mentoring and training early-career investigators in melanoma research indicates the potential for successful mentorship and career development of the Scholars.
- To what extent the experiences of the Director and Deputy Director complement each other and will contribute to a successful Academy.
- To what extent the MA Leadership describe their commitment to leading the MA, and to the success of this unique, interactive virtual academy in providing collaborative mentoring of Scholars with the goal of developing sustainable, independent careers as leaders in the melanoma field at their institutions, nationally, and internationally.

Management of the Academy

- Whether the roles that will be filled by the Academy Director and Deputy Director are clearly defined.
- To what degree the Academy Leadership will catalyze cross-disciplinary communication and collaboration among all of the Scholars and their Career Guides, the melanoma consumer community and the broader melanoma research and patient care communities (including but not limited to periodic virtual interactive meetings and annual and biennial in-person workshops).
- To what extent the MA Leadership includes plans for developing externally funded collaborative research projects conducted by members of the MA (e.g., between MA Leadership and Scholar, Scholar/Scholar, Scholar/Career Guide) with input from the Melanoma Consumer Consultant Panel.
- To what extent the Academy Leadership explains the opportunities provided within the MA for the Scholars overcome barriers associated with initiating and sustaining a career in melanoma research (grant writing, research and laboratory management, publications, professional networking, and committee memberships, etc.).
- Whether the MA describes plans for including Mid-Career Accelerator Award investigators and MA Scholar Alumni into MA activities.

Evaluation Plans

- To what extent the MA Leadership explains how they will evaluate the research progress made by the Scholars, their career progression, and sustainment as independent investigators in melanoma research and/or patient care. To what extent the MA Leadership identifies measurable outcomes for the Scholars that are expected to be achieved by the end of their Melanoma Academy Scholar Award period of performance.
- How well the Scholar Evaluation Plan articulates the evaluation questions/criteria, processes for data collection and storage, the analysis and interpretation of the data, and dissemination/utilization of evaluation results?
- To what extent the MA explain how they will evaluate the MA's progress toward accomplishing the outlined vision and mission of the Academy. To what extent MA Leadership defines the metrics that will be used to monitor progress, identify areas for improvement, and make informed decisions about future MA activities.

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- How well the MA Evaluation Plan articulates the evaluation questions/metrics, processes for data collection and storage, the analysis and interpretation of the data, and dissemination/utilization of evaluation results?
- (If applicable) Whether copies of questionnaires, forms, etc., that may be used for data collection for either the Scholar or MA Evaluation Plan are provided and to what extent they support the proposed evaluation plan(s).

Melanoma Consumer Consultant Panel

- Whether the application names at least two Melanoma Consumer Consultants where at least one of the named consultants is a Service Member or Veteran.
- How relevant the qualifications/background of the Melanoma Consumer Consultants are to their role on the Melanoma Consumer Consultant Panel.
- How well the Melanoma Consumer Consultant Panel is described.
 - To what extent the Melanoma Consumer Consultants' roles on the panel will be integral to the training, networking, and collaboration of the Scholars.
 - Whether the application articulates how the patient advocates and Veteran(s) will have a meaningful role in the MA.
- To what extent captured input from the Melanoma Consumer Consultant Panel is indicated and will be meaningfully integrated and incorporated into the workings of the MA.
- Whether a plan for how data and resources generated during the performance of the MA be shared with the relevant communities (i.e., scientific and advocacy organizations and the public) is explained.

Impact

- To what extent the MA will foster convergent science wherein investigators from different disciplines solve specific problems together and take a cross-disciplinary approach to accelerate moving the melanoma field forward.
- To what extent the anticipated short-term and long-term impact of the MA on melanoma research, patient care, and/or quality of life to the benefit of Service Members, Veterans, their Families, and the American public are justified.
- To what extent the MA will incorporate military health relevance into the vision and mission of the Academy.

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**:

Budget

• Whether the budget is appropriate for the proposed effort.

Environment

- To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.

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• 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.

6.2.3. 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 FY25 MRP, as evidenced by the following:
 - Adherence to the intent of the funding opportunity.
 - Relative impact.
 - o Program portfolio composition.
 - Relative relevance to military health.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. *CDMRP will NOT provide an invitation to submit a full application after pre-application 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.

6.3.2. Full Application

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 <u>Section 6.2.3</u>, <u>Programmatic Review</u>. Additional information about the two-tier process used by the CDMRP can be found on the <u>CDMRP website</u>.*

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.

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6.4. Risk, 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DOD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

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7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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8. Post-Award Requirements

8.1. 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 <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

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.

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 (OHARO), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. 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.

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).

8.3. Additional Requirements

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

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An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

The Initiating PI (Director) and Partnering PI (Deputy Director) will be required to present their progress toward accomplishing the Academy milestones at a Milestone meeting during year 3 of the period of performance. A representative of the Melanoma Consumer Consultant Panel may also be invited to attend the Milestone meeting. The meeting will be held in the National Capital Region or virtually, at the discretion of the government.

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 H, for general information on organization or PI changes.

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9. Other Information

9.1. 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 CD25_01d. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Pre-application was not submitted.
- Project Narrative is missing.
- Budget is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY25 MRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the preapplication or application processes.
- Applications that include names of personnel from either of the CDMRP peer or
 programmatic review companies for which conflicts cannot be adequately mitigated. For
 FY25, the identities of the peer review contractor and the programmatic review contractor
 may be found on the <u>CDMRP Website</u>.
- 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) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

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- 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.
- 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 Initiating PI or Partnering PI do not meet the eligibility criteria.
- A clinical trial is proposed.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

9.2.4. 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.

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Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded		
	Initiating PI	Partnering PI	
SF424 Research & Related Application for Federal Assistance (Grants.gov submissions only)			
Summary (Tab 1) and Application Contacts (Tab 2) (eBRAP 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"			
Melanoma Consumer Consultation Plan – Attachment 6, upload as "MCCplan.pdf"			
Impact Statement – Attachment 7, upload as "Impact.pdf"			
Representations (Grants.gov submissions only) – Attachment 8, upload as "RequiredReps.pdf"			
<u>Suggested Intragovernmental/Intramural Budget Form</u> (if applicable) – Attachment 9, upload as "IGBudget.pdf"			
Research & Related Personal Data			
Research & Related Senior/Key Person Profile (Expanded)			
Attach <u>Biographical Sketch</u> for PI and Senior/Key Persons (Biosketch_LastName.pdf)			
Attach Current/Pending Support for PI and Senior/Key Persons (Support_LastName.pdf)			
Budget Include budget justification			
Project/Performance Site Location(s) Form			
Research & Related Subaward Budget Attachment(s) Form (if applicable)			

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Appendix 2. Acronym List

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations
DOD U.S. 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

FY Fiscal Year

IACUC Institutional Animal Care and Use Committee

IRB Institutional Review Board

LOI Letter of Intent

M Million

MA Melanoma Academy

MALA Melanoma Academy Leadership Award

MIPR Military Interdepartmental Purchase Request

MRP Melanoma Research Program
NIH National Institutes of Health

NSF U.S. National Science Foundation

OHARO Office of Human and Animal Research Oversight (previously Office of

Research Protections)

OUSD R&E Office of the Under Secretary of Defense for Research and Engineering

PDF Portable Document Format

PHS Public Health Service
PI Principal Investigator

RPPR Research Performance Progress Report

SAM System for Award Management

SciENcv Science Experts Network Curriculum Vitae

SF424 Standard Form 424 (Application for Federal Assistance, Research & Related)

SOW Statement of Work

STEM Science, Technology, Engineering, and/or Mathematics

UEI Unique Entity Identifier
URL Uniform Resource Locator

USAMRAA U.S. Army Medical Research Acquisition Activity

USAMRDC U.S. Army Medical Research and Development Command

USC United States Code

VA U.S. Department of Veterans Affairs

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Appendix 3. DOD and VA Websites

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

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

Defense Advanced Research Projects

Agency https://www.darpa.mil/

Defense Health Agency https://www.dha.mil

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/

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.med.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 Research and Development Command https://mrdc.health.mil/

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

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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/