Program Announcement for the Department of Defense
Defense Health Program

Melanoma Research Program
Idea Award

Funding Opportunity Number: HT942525MRPIA

Pre-Application Due: June 30, 2025

Application Due: October 1, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

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 Frequently Asked Questions 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.

1. Basic Information About the Funding Opportunity

Summary: Supports innovative, exploratory, high-risk/potentially high-reward research. Novelty and innovation are expected to be key aspects of the proposed project. By the end of the Idea Award funding period, the anticipated outcomes of successful efforts should be establishing proof of principle and obtaining preliminary data to secure follow-on funding.

Distinctive Features:

- Application submission is a two-step process requiring both a ***pre-application*** and a ***full application***. Investigators must receive an invitation to submit a **full application**.
- Preliminary data are ***discouraged***.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $5.76 million (M) to fund approximately 9 Idea Award applications with direct cost caps of $400,000. The maximum period of performance is 2 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 (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 30, 2025
- **Invitation to Submit an Application:** July 31, 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: Initial

Funding Opportunity Number: HT942525MRPIA

Assistance Listing Number: 12.420

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

To be named as the Principal Investigator (PI) on the application, the investigator must be at or above the level of Postdoctoral Fellow, or equivalent.

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.

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 Melanoma Research Program (MRP). Congress initiated the MRP in 2019 to provide support for research of high-potential impact and exceptional scientific merit in the field of melanoma. 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 Idea Award mechanism was first offered in FY19. Since then, 549 compliant full Idea Award applications were received and 70 were recommended for funding.

3.2. Intent of the Idea Award

The FY25 MRP Idea Award supports innovative, untested, exploratory, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods that address at least one of the FY25 MRP focus areas.

The intent of the Idea Award is to generate novel research avenues for investigation; therefore, novelty and innovation should be key aspects of the proposed project. Research supported by the Idea Award must introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. The proposed project must be exploratory, hypothesis-driven, or hypothesis-generating research and be based on a well-developed study design and plan of analysis. PIs new to the melanoma field are encouraged to apply.

The Idea Award is NOT intended to expand or extend previously published findings nor to continue a line of research already established and/or funded in the PI's laboratory. Incremental advances, the next logical step, or merely switching the object or method of inquiry from one cancer to melanoma are not considered innovative. The expected outcomes of research supported by this award are to establish proof of principle and to generate robust preliminary data to be used as a foundation for future melanoma-focused research projects.

3.2.1. Focus Areas for the Idea Award

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 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 FY25 MRP Idea Award must address at least one of 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 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 as defined above.

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. Key Elements for the Idea Award

Inclusion of preliminary data is discouraged. PIs proposing projects already supported by significant preliminary data and/or other funding sources should consider applying to other FY25 MRP funding opportunities for which the inclusion of preliminary data is more appropriate or required. Inclusion of preliminary data other than serendipitous findings is not consistent with the exploratory/innovative nature of this award. If preliminary data are included, they should be unanticipated outcomes or results from an unrelated project or study.

3.2.3. Other Important Considerations for the Idea Award

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 (PDMs) comprised of patient-derived xenografts (PDXs), *in vitro* patient-derived tumor cell cultures (PDCs), and cancer-associated fibroblasts (CAFs), as well as patient-derived organoids. In addition to model generation, NextGen sequencing data are available for all models, as well as DNA, RNA, and flash-frozen fragments for protein extraction from early-passage PDXs. The PDMR's 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.
- 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 U.S. Department of Veterans Affairs (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 to 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 research project funded and sponsored by the Melanoma Research Foundation's CURE OM initiative. The registry launched in the United States 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, the University of California San Francisco Beckman Vision Center, and the National Organization for Rare Disorders. This participant-driven registry launched in 2019 to enhance the understanding of ocular melanoma, collect data for medical research, and facilitate the development of new diagnostic and treatment options.
- The RARE® Registry. The RARE Registry is an initiative led by the Melanoma Research Alliance primarily 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 health care 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.
- An explanation of how the project addresses an aspect of melanoma that has relevance to 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 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 3 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. 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.

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

Clinical trials are NOT allowed under the Idea 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.
- 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 grants (31 USC 6304).

3.5. Funding Details

Period of Performance: The maximum period of performance is **2** years.

Cost Cap: The application's direct costs budgeted for the entire period of performance should not exceed **$400,000**. 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 **2** years.

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the MRP Idea Award.

Must not be requested for:

- Clinical trial costs.

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 (eBRAP) 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.

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (one-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should provide responses to the following questions. Each response in the uploaded narrative should be numbered to match the questions below. Not doing so may impact review of the preproposal. NOTE: Recommended character limits provided below do not supersede the maximum one-page limit for the preproposal narrative.

  1. What is the hypothesis to be tested and/or objective to be obtained? Briefly describe the specific aims of the proposed research and how the scope of the proposed research is appropriate for the intent of an Idea Award and feasible to complete within the allowed budget and period of performance limits. How will the proposed work uniquely address a critical problem in at least one of the FY25 MRP focus areas. (Recommended 2000-character limit.)
  2. What are the innovative aspects of the proposed research (seeking a new paradigm, challenging current paradigms, introducing novel concepts or agents, etc.)? Justify how the proposed research is beyond an incremental advancement, is not an extension of previously published findings or theories, and/or is not a continuation of an established research program in the PI's laboratory? (Recommended 2000-character limit.)
  3. How will the anticipated short- and long-term outcomes of the proposed research, if the effort is successful, advance the state of science/technology in melanoma to the benefit of Service Members, Veterans, their Families, and the American public? (Recommended 500-character limit.)

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

4.3. Step 2: Full Application Components

Applicants ***must*** receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

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 (six-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.

  - **Rationale:** Present the scientific rationale behind the proposed research; include relevant literature citations. ***Preliminary data are discouraged***.
  - **Hypothesis and Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **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. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations and/or the power of the proposed studies during review of the application. If there are

sample size limitations (budget limitations, availability of specimens, etc.) justify how results from the proposed sample size(s) will yield meaningful information. A separate Sex as a Biological Variable (SABV) Strategy is required as part of Attachment 2.

- 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.
- 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 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 (funding restraints, availability of rare specimens, etc.), 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, 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, 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 Support (two-page limit per letter *is recommended*):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. 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.
- **SABV Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **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.
- **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. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, 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.

  Technical abstracts 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 research project.
  - **Hypothesis/Objective(s):** State the hypothesis to be tested/objective(s) 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.
  - **Innovation:** Summarize the innovative aspect(s) of the proposed project.
  - **Impact:** Summarize how the proposed project will make an important contribution toward at least one of the FY25 MRP focus areas.

- **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 ***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 FY25 MRP focus area(s) to be addressed by the research project.
  - Summarize the scientific rationale, objective, and aims for the proposed project.
  - Summarize how the proposed research is a novel concept, idea, or paradigm that will lead to new avenues of discovery or development.
  - Summarize the applicability of the research to melanoma patients and/or survivors by considering the following points:
    - What populations will the proposed research help?
    - What are the potential applications, benefits, and risks?
    - How will the proposed research outcomes benefit Service Members, Veterans, their Families, and the American public?

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the Idea Award, refer to the "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW.

- **Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** Describe how the project will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other uniquely creative qualities. Justify how the proposed research represents more than an incremental advancement, studies a new avenue of research for the laboratory, and/or addresses new concepts beyond already established lines of research in the PI's laboratory and/or published data.

- **Attachment 7: 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 FY25 MRP focus areas. Define a reasonable expectation for success for the proposed research and describe a practical vision for how the short- and long-term outcomes of the proposed research, if successful, will advance the state of the science/technology in melanoma research, patient care, and/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. 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. If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.

- **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 conflicts of commitment 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.

  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.

(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".

4.4. 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.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525MRPIA from Grants.gov or eBRAP, depending on which submission portal will be used.

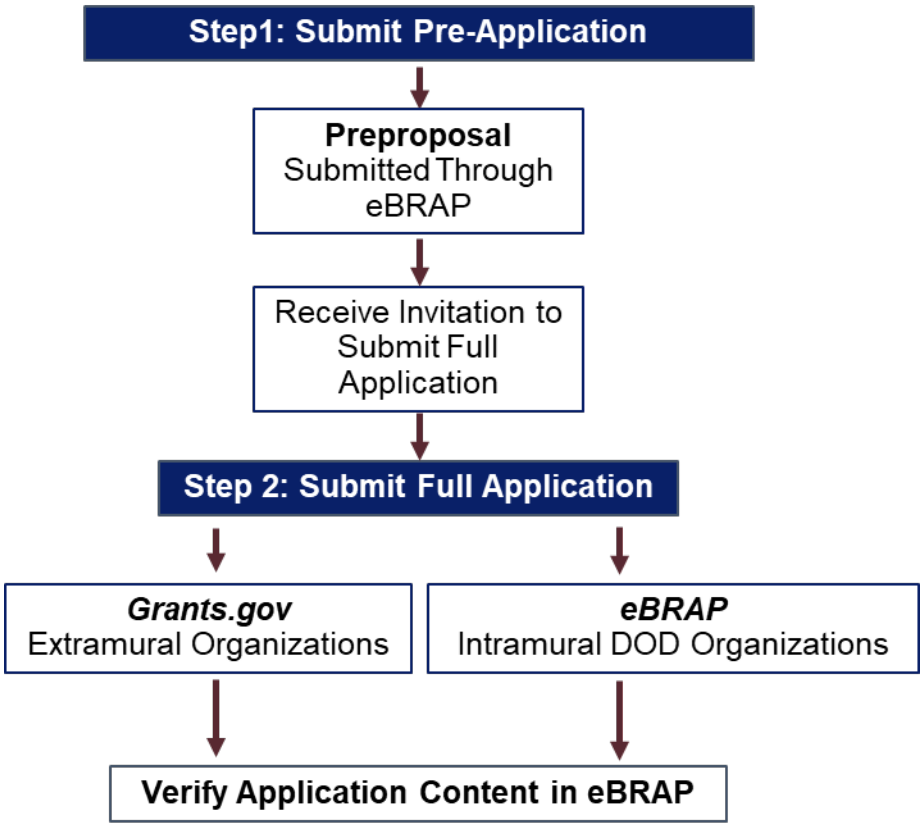
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, 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.

Application Submission Workflow



5.3.1. Pre-Application Submission

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.

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 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 Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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 CDMRP's full position on research duplication.

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 Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the MRP, pre-applications will be screened based on the following criteria:

- How well the application addresses at least one of the FY25 MRP focus areas.
- To what extent the hypothesis to be tested and/or objective to be achieved and the stated specific aims are appropriate for the intent of an Idea Award and are feasible to complete within the allowed budget and period of performance limits.
- To what extent that the proposed research is innovative, as defined in this program announcement.
- To what extent the proposed research, if successful, will advance the state of science/technology in melanoma to the benefit of Service Members, Veterans, their Families, and the American public.

6.2.2. Peer Review Criteria

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

- **Innovation**

- To what extent the project is innovative and will lead to a new paradigm, challenge current paradigms, look at existing problems from new perspectives, introduce novel concepts or agents, or exhibit other uniquely creative qualities.
- To what extent the application justifies that the proposed research represents more than an incremental advance, studies a new avenue of research for the laboratory, and/or addresses new concepts beyond already established lines of research in the PI's laboratory and/or published data.

- **Research Strategy and Feasibility**
  - To what extent the scientific rational supports the proposed research, as demonstrated by a critical review and analysis of the literature and logical reasoning. If preliminary data are presented, ***which is discouraged***, whether they support the hypothesis or objective.
  - To what extent the hypothesis or objective, research strategy, methodology, and analyses are well-developed and support successful completion of the specific aims.
  - How well the application addresses potential problem areas and presents alternative methods and approaches.
  - To what extent it will be feasible to complete the proposed research within 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, how well 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, racial, and ethnic group, and an accompanying rationale for the selection of specimens/subjects. Whether a completed Inclusion Enrollment Report providing anticipated enrollment table(s) for the inclusion of women and minorities is included with the application.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.

- **Impact**
  - To what extent the proposed research uniquely addresses a critical problem in at least one of the FY25 MRP focus areas.

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

  - A practical vision for how the short- and long-term outcomes of the proposed research will advance the state of the science/technology in melanoma research, patient care, and/or survivorship is described.
  - The proposed research is relevant to the health and well-being of Service Members, Veterans, their Families, and all people impacted by melanoma.

- If applicable, the anticipated outcomes of the proposed research will make an impact in understanding health differences between sexes.

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**
  - How appropriate the expertise and levels of effort are for successful conduct of the proposed work.
- **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 budget is appropriate for the proposed research.
- **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.
- **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.
  - Relevance to at least one of the FY25 MRP focus areas.
  - Relative innovation.
  - Relative impact.
  - Program portfolio balance.
  - Relevance to military health.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information About the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title, focus areas, or research objectives after the pre-application is submitted.

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

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.

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 OUSD R&E Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

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.

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 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.

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), 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.

PHS Inclusion Enrollment Reporting ***(Required for research proposing clinical research)***: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on 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).

8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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.

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_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.
- 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 pre-application 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 CDMRP Website.
- 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.
- 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.
- The invited application proposes a different research project than that described in the pre-application.
- 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 FY25 MRP focus areas.
- The PI does not meet the eligibility criteria.
- A clinical trial is proposed.
- The main subject of the research is non-melanoma skin cancers.

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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded
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"	☐
Innovation Statement – Attachment 6, upload as "Innovation.pdf"	
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐
Representations ***(Grants.gov submissions only)*** **– Attachment 8, upload as "RequiredReps.pdf"**	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 9, upload as "IGBudget.pdf"**	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐
Research & Related Budget **Include Budget Justification**	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form ***(if applicable)***	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CAF	Cancer-Associated Fibroblast
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
HCMI	Human Cancer Models Initiative
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
MVP	Million Veteran Program
NCI	National Cancer Institute
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
PDC	Patient-Derived Tumor Culture
PDF	Portable Document Format
PDM	Patient-Derived Model
PDMR	Patient-Derived Models Repository
PDX	Patient-Derived Xenograft
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SABV	Sex as a Biological Variable
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
SPORE	Specialized Programs of Research Excellence
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 3. 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 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/

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/