I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Melanoma Research Program

Team Science Award

Announcement Type: Initial

Funding Opportunity Number: HT942524MRPTSA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), July 29, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 26, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, September 3, 2024
- **Peer Review:** November 2024
- **Programmatic Review:** February 2025

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

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Melanoma Research Program (MRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the MRP in 2019 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the MRP from FY19 through FY23 totaled $140 million (M). The FY24 appropriation is $40M.

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

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

II.A.1. FY24 MRP Focus Areas

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

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

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

Rare Melanomas: Rare melanoma subtypes (e.g., uveal, acral, mucosal, pediatric melanomas) can have distinct characteristics compared to cutaneous melanoma, which makes up the majority of melanoma diagnoses, and the rare melanoma sub-types are typically less-well studied. This has led to a variety of prevention, diagnosis, and treatment challenges. The MRP seeks to fund research across the entire cancer research spectrum (i.e., biology, etiology, prevention, diagnosis and detection, prognosis, treatment, and quality of life) that addresses unmet needs and knowledge gaps associated with rare melanomas.

Survivorship: The widely accepted definition of cancer, and therefore melanoma, survivorship spans ***the time from an individual receiving their initial diagnosis through the balance of their life***. ***Under this definition, an individual is considered a melanoma survivor beginning at the***

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

To be considered for funding, all applications for the FY24 MRP Team Science Award must address at least one of the following FY24 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 to therapy (prior to tumor metastasis), progression, recurrence, emergence from tumor dormancy, and/or metastatic spread. Studies may include the role of the tumor microenvironment and/or microbiome in these processes.
- Develop new preclinical models that more faithfully represent disease evolution observed in humans, from melanomagenesis through progression. This includes models for either cutaneous melanoma or any of the rare melanoma subtypes.

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.

II.A.2. Award History

The MRP Team Science Award (TSA) mechanism was first offered in FY19. Since then, 96 compliant, full applications (representing 239 potential awards) have been received, and 25 applications (representing 25 projects and 62 awards) were recommended for funding. In FY23, the MRP received 31 compliant, full applications (representing 81 potential awards), and 7 applications (representing 7 projects and 18 awards) were recommended for funding.

II.B. Award Information

Intent of the TSA:

The intent of the FY24 MRP TSA is to support a broad range of hypothesis-driven, ***multidisciplinary*** studies that are responsive to at least one of the FY24 MRP Focus Areas in Section II.A.1 and have the goal of advancing the state of the science in melanoma research and/or patient care. Team science is a synergistic effort that harnesses techniques, approaches, and perspectives from multiple disciplines and/or therapeutic areas to address complex, multi-dimensional problems that will impact patient outcomes. The TSA is intended to bring together investigators from divergent disciplines to achieve innovations and advancements in melanoma research and/or patient care that could not be achieved by any one investigator working independently. While basic research is allowed, all applications are expected to articulate the short- and long-term benefits of the expected research outcomes for the melanoma patient community.

The TSA requires that at least two and up to three Principal Investigators (PIs) partner to jointly design a single research project; multi-institutional partnerships are encouraged. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section II.D.2, Content and Form of the Application Submission.

At least one member of the partnership must have experience in either melanoma research or patient care. Inclusion of investigators from outside the melanoma field is encouraged. ***Each PI is expected to contribute both intellectual investment and research effort to the development and execution of the proposed research project. A proposed project in which a Partnering PI merely supplies reagents, tissue samples, or access to patients will not meet the intent of this award mechanism***.

Applicable types of research:

Research that meets the intent of the TSA includes, but is not limited to, the following:

- ***Translational research*** that leverages clinical samples from established biobanks, established biorepositories, and/or ongoing or completed clinical trials. Translational research applications should include evidence for the reciprocal transfer of information between basic and clinical science or vice-versa in developing and implementing the research plan. Such integration between the laboratory and clinic should lead to greater knowledge, discovery, and/or development of earlier interventions.

- ***Data science research*** where quantitative and analytical approaches, processes, and/or systems are developed and/or used to obtain knowledge and insight from large and/or complex sets of melanoma data. Studies utilizing data derived from large patient studies that include long-term health records or repositories with well-annotated and high-quality biospecimens are encouraged. Proposed research can include studies related to computational biology, bioinformatics, artificial intelligence and machine learning, medical imaging, digital pathology, etc. Applications may combine diverse data types for integrative analysis. Use/analysis of already-existing datasets is strongly encouraged.

- Research that uses ***bioengineering*** approaches to develop tools that assist in the detection, diagnosis, prognosis, and/or treatment of melanoma. Techniques from fields such as quantitative science, mathematics, computer science, or engineering may be merged with biomedical sciences to address a relevant question or area of need.

- Research that seeks to better understand and/or reduce ***inequities and disparities*** that impact a person, their family, or their caregiver's ability to prevent, detect, manage, and survive melanoma. Inequities may arise from socioeconomic status, race or ethnicity, geography, environment, lifestyle, sexual and/or gender identification, access to care (in rural or urban settings), or other factors.

- ***Other hypothesis-driven basic to translational research*** designed to investigate melanoma prevention and/or interception, rare melanomas, or melanoma survivorship. The proposed research project may utilize animal models, human data and/or anatomical substances, and/or human subjects.

Key aspects of the TSA:

Multidisciplinary Collaboration: The success of the project should depend on the unique skills and perspectives of each partner. The application must clearly define the synergistic components that will facilitate and accelerate progress in melanoma in a way that could not be accomplished through independent efforts. The plans for interactions among all PIs and institutions involved must be clearly articulated. Collectively, the members of the research team should represent the appropriate diversity of expertise necessary for addressing the proposed research question. Participating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation. The following components of the proposed multidisciplinary collaboration are encouraged but not required:

- It is strongly encouraged that the research team has a least one investigator, key personnel, or consultant who can provide input on the ultimate utility/applicability (short- or long-term) of the anticipated outcome(s) to the melanoma field and/or patient care**.**

- The inclusion of an early-career investigator is encouraged. An early-career investigator is defined as an independent, early-career researcher or physician-scientist within 7 years of receiving their first faculty appointment by the time of the full application deadline. ***Investigators in mentored positions, (e.g., postdoctoral fellows) are not eligible to be named as a PI on a TSA application***.

- The inclusion of a military and/or U.S. Department of Veterans Affairs (VA) investigator is encouraged. A military or VA investigator is defined as an investigator who is active-duty, active reserve, active duty detailed to agencies outside of the Department of Defense (DOD), civilian DOD investigators, or an investigator at a VA research facility. If included as PI on the research team, the military/VA investigator should have a substantial role in the research and should not be included only for access to active-duty military and/or VA populations.

Impact: The application must articulate the impact the proposed work, including basic research, will have on melanoma research and/or patient care. Outcomes from this award are expected to expedite the advancement of promising ideas toward clinical applications and/or improve the current state of the science/technology in the melanoma field. The proposed research must relate to at least one of the FY24 MRP Focus Areas in Section II.A.1.

Preliminary Data Required: Applications ***must include preliminary data*** to support feasibility of the study. However, these data do not necessarily need to be derived from melanoma studies. Any unpublished, preliminary data presented should originate from the laboratory of at least one of the PIs or other member(s) of the research team.

Other important considerations:

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

- National Cancer Institute (NCI) Patient-Derived Models Repository (PDMR). The PDMR is a national repository of patient-derived models (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 VA investigators.

- Million Veteran Program. The Million Veteran Program (MVP) is the nation's largest genomic biorepository of Veteran data and is one of the most diverse cohorts of any genetic research program in the world. **NOTE:** Access to MVP data is currently limited to ONLY VA-affiliated researchers.

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

- Patient-Derived Cancer Models. Cancermodels.Org provides harmonized and integrated model attributes to support consistent searching for PDX, organoid, and cell line models and facilitate researchers' search for models and associated data across multiple commercial and academic resources.

- The CURE OM VISION Platform. The CURE OM VISION Platform is a patient-powered ocular melanoma (OM) research project funded and sponsored by the Melanoma Research Foundation's CURE OM initiative. The registry launched in the U.S. in May 2021 and was made available to participants worldwide soon thereafter. The CURE OM initiative's patient community and collaborators are now actively participating, sharing data, and joining researchers in the work towards more effective treatments and, one day, a cure.

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

- The RARE® Registry. The RARE® Melanoma Registry is an initiative led by the Melanoma Research Alliance for patients with acral and mucosal melanoma. It provides a free, interactive, web, and mobile-friendly tool to share information, experiences, and disease history; advance research and awareness; and get potential matches to clinical trials.

Melanoma Consumer Collaborations: For the purposes of the TSA, ***a "melanoma consumer" is a melanoma survivor (active or post-treatment), family member, and/or caregiver who can provide lived experience expertise*** to a research project. Applicants to the TSA are encouraged, but not required, to collaborate with the melanoma consumer community to optimize the impact and translatability of the research outcomes for the benefit of this community.

Collaborative research approaches create partnerships between scientific researchers and melanoma consumer community members to create knowledge useable by both sets of stakeholders. Recognizing the strengths of each partner, scientific researchers, and melanoma consumer community members collaborate and contribute equitably on all aspects of the project, which may include needs assessment, planning, research design, implementation, evaluation, and dissemination. Collaborative research approaches feature shared responsibility and ownership for the research project to ensure non-tokenistic involvement of the melanoma consumer community members within the research team. Research results are jointly interpreted, disseminated, and fed back to affected communities and in some instances may be translated into interventions or policy.

Collaborative relationships with the melanoma consumer community may be established through integrating community members into research teams as co-researchers, advisors, and/or consultants; melanoma consumer collaborators should ***not*** be named as Initiating or Partnering PIs. Examples for implementing collaborative research approaches are listed below, but each research team may pursue other options as appropriate for the proposed research:

- The research team includes at least one melanoma consumer who will provide advice and consultation throughout the planning and implementation of the research project. The consumer(s) should be able to speak to the needs of the melanoma consumer community, not just speak to their own personal experiences.

- The research team establishes partnerships with at least one community-supporting organization that provides advice and consultation throughout the planning and implementation of the research project. Community-supporting organizations may include advocacy groups or other formal organizational stakeholders that can speak to the needs of the melanoma consumer community.

- The research team assembles a melanoma consumer community advisory board. The advisory board may include melanoma consumers, a coalition of community-supporting organizations, or any combination thereof that provides advice and consultation throughout the planning and implementation of the research project.

Additional information on collaborative research approaches can be found in:

- Cancer Research UK. Patient involvement toolkit for researchers. https://www.cancerresearchuk.org/funding-for-researchers/patient-involvement-toolkit-for-researchers.

- Spears PA. 2021. Patient engagement in cancer research from the patient's perspective. *Future Oncology* 17(28):3717-3728. doi: 10.2217/fon-2020-1198. Epub 2021 Jul 2. PMID: 34213358

- Salamone JM, Lucas W, Brundage SB, et al. 2018. Promoting scientist-advocate collaborations in cancer research: Why and how. *Cancer Research* 78(20):5723-5728. doi: 10.1158/0008-5472.CAN-18-1600.

- Food and Drug Administration. Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development. https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development.

Relevance to Military Health: The 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.

- Explanation of how the project addresses an aspect of melanoma that has relevance or is unique to Service Members, Veterans, and/or their Families.

If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 4, for additional information.

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

Preclinical Research: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

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

Clinical trials are NOT allowed under the Team Science Award.

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

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

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

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

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

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

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

Organizational-Level Areas of Emphasis:

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

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

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

Metastatic Cancer Task Force: A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research.

Funding Details:

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

The anticipated combined direct costs budgeted for the entire period of performance for an FY24 MRP Team Science Award should not exceed **$1,500,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $16.8M to fund approximately seven Team Science Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

II.C.1.b. Principal Investigator

The investigator named as the Initiating PI on the application must be an independent investigator at any career level.

The investigator(s) named as the Partnering PI(s) on the application must be an independent investigator at any career level.

An investigator in a mentored position (e.g., postdoctoral fellow, clinical fellow) is not considered independent and is ***not*** eligible to be named as Initiating or Partnering PI.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

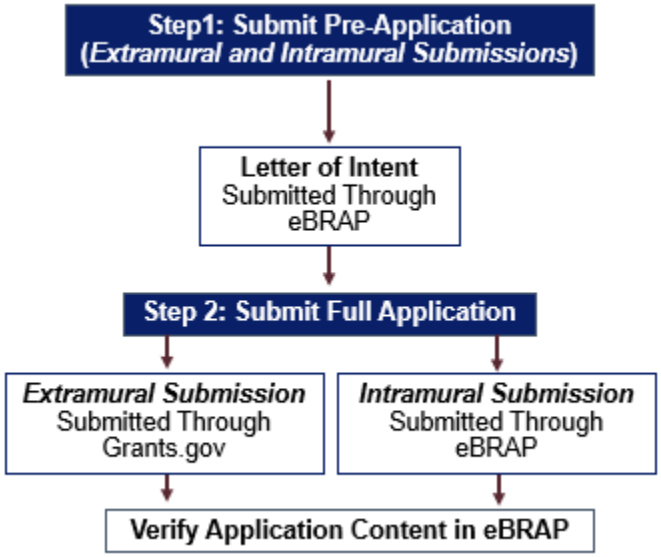
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

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

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

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

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524MRPTSA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524MRPTSA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

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

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

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

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

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

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

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

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for each Partnering PI.

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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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.

After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI(s) must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI(s) must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI(s) should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

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 complete these steps as soon as possible. If they are not completed:

- The Partnering PI(s) 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.

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

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

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY24 MRP Focus Area(s) (listed in Section II.A.1) under which the full application will be submitted. If the application will include collaboration with the melanoma consumer community (not required), identify the individual(s) and/or community-supporting organization(s) that will serve as advisor/consultant for the proposed research.

  LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

NOTE: For applications that do include melanoma consumer collaborators (not required), the collaborator(s) should be named during the pre-application submission. For administrative purposes, please use the label "Consumer" when assigning the melanoma consumer collaborator(s)'s roles in eBRAP under "Collaborators and Key Personnel".

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

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

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

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

II.D.2.b.ii. Full Application Submission Components for the Initiating PI

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 full application submission components for the Partnering PI(s) are detailed in Section II.D.2.b.iii. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. *All associated applications (the Initiating PI's and each Partnering PI's) must be submitted by the full application submission deadline.*

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

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

(b) Attachments:

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

- **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed project in detail using the outline below.

  - **Background:** Present the scientific rationale to support the proposed multidisciplinary research project and its feasibility, as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. Provide sufficient preliminary data to support the feasibility of work proposed. Any unpublished, preliminary data provided should originate from the laboratory of at least one of the PIs or a member of the research team. ***The inclusion of preliminary data is required***. However, preliminary data does not have to be derived from melanoma studies.

  - **Hypothesis and Objectives:** State the hypothesis to be tested or the objective to be reached.

  - **Specific Aims:** State the specific aims of the study. If the proposed research is part of a larger study, ***present only tasks that this award would fund.***

- **Research Strategy and Feasibility:** Describe the experimental design, methodology, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Describe how the studies are designed to achieve the project aims. Address potential problems and pitfalls and present alternative methods and/or approaches.

    - Clearly describe the statistical plan and the rationale for the statistical methodology. If applicable, describe an appropriate power analysis, how it supports the sample size, and how it adequately represents an assessment of the population or subpopulation proposed. If a power analysis was not used to determine the proposed sample size, justify why a power analysis is not essential to the statistical evaluation. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations and/or the power of the proposed studies during review of the application. If there are sample size limitations (e.g., because of budget limitations, availability of specimens) justify how analysis of the proposed sample size(s) will yield meaningful information.

    - If cell lines are to be used, justify why the proposed cell line(s) are appropriate to achieve the goals the proposed study(ies) and clearly articulate the source(s) of the proposed cell line(s).

    - If animal studies are proposed, including the use of PDX models, justify why the proposed animal model was chosen and clearly articulate the source of the model(s). Describe how the animal studies will be conducted in accordance with the ARRIVE guidelines 2.0 (https://arriveguidelines.org/arrive-guidelines) to achieve reproducible and rigorous results.

    - If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human participants will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of participants, and for acquiring any additional research resources necessary for conducting the proposed research project. For projects that propose using human data sets and/or specimens from biobank(s), biorepository(s), and/or ongoing or completed clinical trial(s), and if the manager or lead investigator is not one of the named PIs or key personnel on the TSA application, applicants should provide letter(s) of collaboration (see Attachment 2) from the manager or lead investigator for the source that details the applicant's access to the data sets/specimens and confirms the manager/lead investigator's commitment to provide the data sets/specimens.

    - For all applications that propose clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of specimens/subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are

exempt from this requirement. ***This award cannot be used to conduct clinical trials***. See Attachment 2 for instructions regarding the Inclusion Enrollment Report that is required with all applications that propose clinical research.

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

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

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

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

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

  Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

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

  Letters of Organizational Support (two-page limit per letter *is recommended*): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the independent laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

  Letters of Collaboration *(if applicable)* (two-page limit per letter *is recommended*): Provide a signed letter from each collaborating individual and/or

organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

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

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

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

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

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

of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

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

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

  - **Background:** Present the scientific rationale behind the proposed project. Describe the preliminary data upon which the study is founded.
  - **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Describe the study design, including the model system(s) that will be used and appropriate controls.
  - **Collaboration:** Summarize how the project depends on the unique skills and expertise of each partner. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
  - **Impact:** Summarize how the proposed project will advance the state of the science in melanoma research and/or patient care in at least one of the FY24 MRP Focus Areas in Section II.A.1.

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

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

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

- State the FY24 MRP Focus Area(s) in Section II.A.1 to be addressed by the research project.
- Summarize the scientific rationale, objective, and aims for the proposed project.
- Describe the applicability of the research to melanoma patients and/or survivors by considering the following points:
  - What types of patients will the proposed research help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - Describe the short- and long-term goals that are related to patient care, outcomes, or survivorship. If the research is too basic for near-term clinical applicability, describe the interim outcomes expected and their applicability to the field of melanoma. Basic research should have an ultimate goal of the advancing the melanoma field and/or impacting patient care.
  - How will the proposed research benefit active-duty Service Members, Veterans, their Families, and the American public?
- If applicable, summarize the melanoma consumer collaboration plan, including the name(s) of the melanoma consumer(s) and/or melanoma community-serving organization(s) involved in the collaboration.

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

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the "Suggested SOW format" to develop the SOW for the proposed research. For the Team Science Award, refer to either the "Example: Assembling a Generic Statement of Work" or the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work", whichever example is most appropriate for the proposed research, for guidance on preparing the SOW.

  Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and each Partnering PI should be clearly noted for each task. The SOW should only describe the tasks that would be funded by this award.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf.** ***Using language readily understood by readers without a background in science or medicine***, explicitly state how the proposed research uniquely addresses a critical problem in at least one of the FY24 MRP Focus Areas in Section II.A.1. Describe a practical vision for how the short- and long-term research outcome(s) and/or product(s) of the proposed research will expedite the advancement of promising ideas toward clinical utility and/or improve the current state of the science/technology in melanoma. Describe the relevance of the proposed research to the health and well-being of Service Members, Veterans, their

Families, and all people affected by melanoma. ***All research, including basic, should relate to patient outcomes and how it benefits those affected by melanoma.***

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

- **Attachment 7: Collaboration Plan (two-page limit): Upload as "CollabPlan.pdf".**

  - Describe the roles, responsibilities, and intellectual contribution of each PI in the proposed research. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Include levels of effort by each PI.

    - Describe the role and responsibility of the early-career investigator in the overall research project (if applicable).

    - Describe the role and responsibility of the military or VA investigator in the overall research project (if applicable).

  - Explain how the research team has the appropriate expertise to assess the utility/applicability (short- and/or long-term) of the anticipated outcome(s) to the melanoma field and/or patient care.

  - Describe the multidisciplinary aspects of the team, including how the project depends on the unique skills of each PI and their respective teams. Describe how the collaboration is synergistic (i.e., why the work must be done together rather than through separate efforts). Explain how the overall organization of the team supports the coordinate efforts. Include a figure illustrating the organization of the collaborative effort, to include the expertise and contribution of each partner to the overall project.

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

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

- **Attachment 8: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** PIs are encouraged to work with their organization(s)'s Technology Transfer Office (or equivalent) to develop the transition plan. The research team is also encouraged to explore developing relationships with industry and/or other funding agencies to facilitate moving the anticipated research outcome(s) and/or product(s) into the next phase of development. The post-award transition plan should include the following components:

  - Outline the project's anticipated research outcome(s) and/or product(s) (e.g., finding, methodology, intervention, device).

- Describe the next logical steps to be taken ***by the research team*** upon successful completion of the project to advance the anticipated research outcome(s)/product(s), including outcomes resulting from basic research projects, to the next stage of development (e.g., next stage preclinical/clinical research, translational research, clinical trial). Include a description of collaborations and other resources that are in place or would be established during the period of performance to execute the next logical steps (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources).

- Describe/discuss the methods and strategies necessary for the research outcome/product to impact patient care and outcomes, even if those are long-term goals; include a timeline with defined milestones. Include details of the funding strategy necessary to transition to the next level of investigation, development, and/or commercialization. This may include commercial sponsorship, venture capital, federal or non-federal funding opportunities, etc. Discuss the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcome(s)/product(s) into public utility and/or clinical practice.

- If applicable, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award, including a plan for resolving intellectual and material property issues among participating organizations. If the intellectual property rights are not owned by the performer(s), describe the planned next steps necessary to make the product available to the melanoma community.

The first page of the plan may include a header identifying the name of the attachment (e.g., "Post-Award Transition Plan") to aid the review of the application, as long as the page limit is not exceeded.

- **Attachment 9: Melanoma Consumer Collaboration Plan: Combine multiple documents, including letters of collaboration, into one PDF and upload as "Consumer.pdf".** ***(Attachment 9 is only applicable for applications choosing the option to utilize a collaborative research approach that engages the melanoma consumer community.)***

  - **Melanoma Consumer Collaboration Statement (two-page limit is recommended):** If a partnership with the melanoma consumer community, as defined in Section II.B, will be utilized, the application should include a Melanoma Consumer Collaboration statement that provides the name(s) of the melanoma consumer community partner(s) and describes the following:

    - The collaborative research approach that will be used (collaborating with at least one melanoma consumer, partnering with a melanoma community-supporting organization, etc.), including a justification for the approach.

- The input from the melanoma consumer community partner that has already been and/or will be captured and how this input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research.

- Any training that will be provided to either scientific researchers and/or melanoma consumer community members on collaborative research approaches, decision-making, and equitable participation.

- The process measures that will be used to assess the effectiveness of the chosen collaborative research approach.

– **Letter(s) of Melanoma Consumer Collaboration (two-page limit per letter is recommended):** Provide a letter signed by each melanoma consumer collaborator and/or melanoma consumer community-supporting organization confirming their role and commitment to participate on the research team. If a community-supporting organization will be engaged, the letter of commitment should be signed by both the organization point of contact leading the collaboration and the organization's leadership endorsing the collaboration. The letter should include the qualifications and background of the melanoma consumer collaborator(s) and describe the relevance of those qualifications to the proposed research.

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

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

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

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

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

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

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

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

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

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

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 Section II.D.5, Funding Restrictions, for detailed information.

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

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

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

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

II.D.2.b.iii. Full Application Submission Components for each Partnering PI

The application submission process for each Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

(b) Attachments:

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 10: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

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

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

- **Partnering PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **Partnering PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

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

- **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

The initiating and Partnering PI(s) must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for each Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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

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

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

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

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

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

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

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

II.D.4. Submission Dates and Times

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

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

II.D.5. Funding Restrictions

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

The ***combined direct costs*** budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **$1,500,000**. 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.

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

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

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

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Costs for at least two, and up to three, investigators 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 TSA.

Must not be requested for:

- Clinical trial costs

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**
    - To what extent the scientific rationale supports the multidisciplinary project and its feasibility, as demonstrated by logical reasoning and a critical review and analysis of the literature.

- Whether sufficient preliminary data are provided and to what extent the preliminary data supports the feasibility of the proposed study. *Preliminary data does not have to be derived from melanoma studies.*

- To what extent the experimental design (if applicable), methodology, and analyses are described in sufficient detail.

- How well the application acknowledges potential problems and pitfalls and presents alternative methods and/or approaches.

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

- To what extent the statistical plan is appropriate for the proposed research, and the application provides sufficient information to allow thorough evaluation of all statistical calculations. If applicable, whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.

- If applicable, whether the use of the proposed cell lines is appropriately justified.

- If applicable, to what extent the animal studies are designed to achieve the research objectives, to include the use of appropriate models.

- If applicable, to what extent the application demonstrates the availability of human data sets, human anatomical substances, and/or human participants, including a detailed plan for the acquisition of samples/resources and/or recruitment of human participants necessary for conducting the proposed research.

- If applicable, whether the strategies for the inclusion of women and minorities are appropriate to the objectives of the clinical research study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of participants. Whether a completed Inclusion Enrollment Report providing anticipated enrollment table(s) for the inclusion of women and minorities is included with the application.

- **Personnel and Collaboration**

  - To what extent the roles, responsibilities, and intellectual contribution of each PI in the proposed research are described and the proposed collaboration involves a substantial contribution by each PI.

  - Based on the biographical sketches, whether each PI and named key personnel have the research experience needed to complete the proposed research project.

  - Whether the research team has the appropriate expertise to ensure that the anticipated outcomes of the proposed research will have utility/applicability to the melanoma field.

  - To what extent the multidisciplinary aspects of the team are described and the extent to which it is clear why the work must be done together rather than through separate efforts.

- How well the plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project are coordinated.

- If applicable, whether appropriate statistical expertise is available to support the proposed research and analyses.

- If applicable, whether appropriate letter(s) of collaboration is (are) provided to confirm access to proposed use of human data sets and/or specimens.

- If applicable, to what extent an early-career investigator is integrated into the research team.

- If applicable, to what extent a military or VA investigator is integrated into the research team.

- **Impact**

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

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

  - A practical vision for how the short- and long-term outcome(s) and/or product(s) of the proposed research, including how the outcomes from this award will accelerate the development of promising ideas toward clinical applications and/or improve the current state of the science/technology in melanoma, 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.

- **Post-Award Transition Plan**

  - To what extent the post-award transition plan outlines the project's anticipated research outcome(s) and/or product(s).

  - To what extent the plan describes the next logical steps to be taken by the research team to advance the anticipated research outcome(s)/product(s) to the next stage of development.

  - To what extent the plan describes collaborations and other resources that are in place or will be established during the period of performance to execute the proposed next logical steps.

  - To what extent the plan describes the methods and strategies necessary for the research outcome/product to impact patient care and outcomes and whether the plan provides a timeline with defined milestones.

- To what extent the plan describes the funding strategy necessary to transition the outcomes of the overall program to the next level(s) of investigation, development, and/or commercialization.

- To what extent the plan discusses the opportunities available and potential barriers that would impact the progress of commercializing and/or translating the research outcome(s)/product(s) into clinical practice/public utility.

- If applicable, to what extent the applicant discusses ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported under this award.

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 **combined direct** costs for all PIs exceed the allowable direct costs as published in the program announcement.

- **Melanoma Consumer Collaboration Plan (if submitted)**

  For the purposes of the TSA Melanoma Consumer Collaboration, a ***"melanoma consumer" is defined as a melanoma survivor (active or post-treatment), family member, and/or caregiver who can provide lived experience expertise to the research team.***

  - How well a collaborative research approach with the melanoma consumer community is described.

  - Whether a melanoma patient advocate and/or a melanoma consumer community-supporting organization is named.

  - How well the application describes the input from the melanoma consumer community partner(s) that has already been and/or will be captured.

  - How well the application describes how the melanoma consumer community input has been and/or will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and/or dissemination of the research

  - Whether a letter (or letters) of support from the melanoma consumer community collaborator(s) is/are provided. If provided, to what extent the letter includes the qualifications and background of the rare melanoma consumer collaborator(s) and describes the relevance of those qualifications to the proposed research.

  - How well the application describes the process measures that will be used to assess the effectiveness of the chosen collaborative research approach.

- **Environment**
    - Whether the scientific environment is appropriate for the proposed research.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.
    - Whether the lay abstract and impact statement are written with clarity for persons without a background in science or medicine.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 MRP, as evidenced by the following:
    - Relevance to at least one of the FY24 MRP Focus Areas in Section II.A.1
    - Adherence to the intent of the Team Science Award described in Section II.B
    - Relative impact
    - Relative synergistic potential of the collaboration
    - Program portfolio balance
    - Relevance to military health

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

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

II.F.4. Reporting

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

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

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

An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress beyond the period of performance.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

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

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

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

- An FY24 MRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation.

A list of the FY24 MRP Programmatic Panel members can be found at https://cdmrp.health.mil/mrp/panels/panels24.

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address at least one of the FY24 MRP Focus Areas in Section II.A.1.
- Preliminary data are not included.
- The Initiating PI does not meet the eligibility criteria.
- The Partnering PI(s) does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- A clinical trial is proposed.
- The main subject of the research is non-melanoma skin cancers.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	**Partnering PI**
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1**,** upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2**,** upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3**,** upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4**,** upload as "LayAbs.pdf"	☐	
Statement of Work –Attachment 5**,** upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Collaboration Plan – Attachment 7, upload as "CollabPlan.pdf"	☐	
Post-Award Transition Plan – Attachment 8, upload as "Transition.pdf"	☐	
Melanoma Consumer Collaboration Plan (*if applicable*) – Attachment 9, upload as "Consumer.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 10**,** upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 11**,** upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐

Full Application Components	Uploaded	
	Initiating PI	**Partnering PI**
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CAF	Cancer-Associated Fibroblast
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
HCMI	Human Cancer Models Initiative
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
MVP	Million Veteran Program
NCI	National Cancer Institute
OM	Ocular Melanoma
PDC	Patient-Derived Tumor Cell 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
SAM	System for Award Management
SOW	Statement of Work
TSA	Team Science Award
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity

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

APPENDIX 2: DOD AND VA WEBSITES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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