

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Melanoma Research Program

Focused Program Award - Rare Melanomas

Announcement Type: Initial

Funding Opportunity Number: HT942524MRPFARM

**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.”

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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. Award History

The MRP Focused Program Award – Rare Melanomas (FPA-RM) was first offered in FY22. Since then, the MRP received 18 compliant, full applications and recommended five applications for funding.

II.B. Award Information

Intent of the FPA-RM:

The FY24 MRP FPA-RM is intended to support a multidisciplinary research program of at least two, but not more than three, distinct but complementary projects addressing an overarching question relevant to rare melanomas (see Figure 1 on the next page). *Applications for the FPA-RM may propose projects across the entire research spectrum (biology, etiology, prevention, diagnosis and detection, prognosis, treatment, and quality of life) and must address a critical unmet need relevant to rare melanomas (e.g., uveal, acral, mucosal, pediatric).*

The key aspects of this award are:

Overarching Question: FPA-RM applications must describe a unifying, overarching question that will be investigated by a set of research projects to address a critical unmet need relevant to rare melanoma research and/or patient care. The question may focus on one specific rare

melanoma, or the question may be designed to address a critical unmet need that is relevant to multiple rare melanomas.

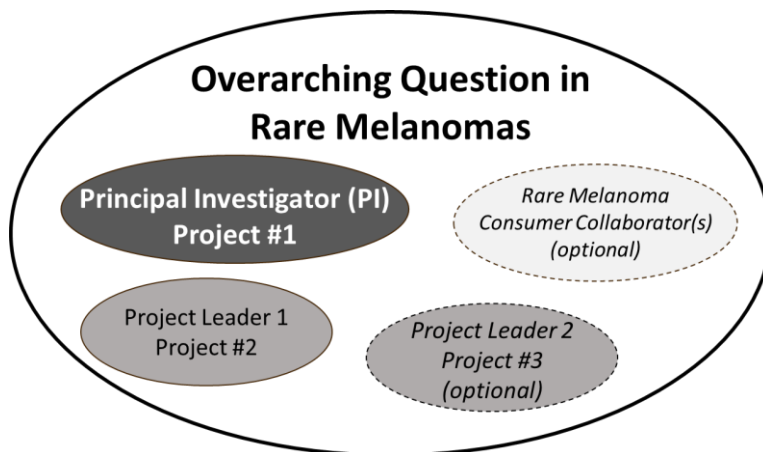


Figure 1. For the FY24 FPA-RM, a research team, consisting of a PI and one or two Project Leaders, will engage in at least two, but not more than three, distinct but complementary projects to answer an overarching question relevant to rare melanomas. The research team is encouraged to include a rare melanoma consumer collaborator(s) (e.g., patients, survivors, caregivers with lived rare melanoma experience) to maximize the impact and translatability of the research for the intended community(ies).

Research Team: The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large, focused projects. The PI is required to devote a minimum of 10% effort to this award. The PI will be the lead for one of the proposed research projects and is expected to create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team. The research team assembled by the PI should be highly qualified and multidisciplinary, with an identified Project Leader(s) for the complementary and synergistic research project(s). The resources and expertise brought to the team by the Project Leader(s) should combine to create a robust collaboration. The PI and the Project Leader(s) do not have to be at the same organization.

Research Projects: Applications should include multiple, distinct research projects that are each led by individual Project Leaders and address complementary aspects of the overarching question. Individual research projects may range from exploratory, hypothesis-developing studies through clinical trials. While individual projects should be capable of standing on their own high scientific merits, they should also be interrelated and synergistic to advance a solution beyond what would be possible through individual efforts. Each project, including hypothesis-developing studies, should propose a unique approach to addressing the overarching question and be capable of producing research findings with potential to advance the rare melanoma field and/or patient care. There should be a clear intent to progress toward translational/clinical work over the course of the effort. This award mechanism is not intended to support a series of research projects that are dependent on the success of the other project(s). All research projects must be based on a strong scientific rationale and preliminary data, as appropriate, that supports the feasibility of the proposed approach(es). **Clinical trials are allowed;** a research project proposing a clinical trial **must** include preliminary data.

Implementation Plan: The research strategy to address the overarching question should be supported by an implementation plan that identifies critical milestones and outlines the knowledge, resources, and/or technical innovations that will be utilized to achieve the milestones. A plan for assessing individual project performance and progress toward addressing the overarching question should be included in the implementation plan. For multi-institutional collaborations, the application should discuss plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, and/or products obtained during the study will be handled. Participating organizations should formalize an intellectual and material property plan.

Milestone Meeting: The PI will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting to be held either virtually or in person in the National Capital Area after the conclusion of year 2 of the period of performance. The intent of the Milestone Meeting is to assess research progress, address problems, and define future directions. Research milestones to be accomplished by the end of year 2 must be clearly defined in the Statement of Work (SOW) and will be finalized during award negotiations. Up to two additional members of the research team may be invited to the meeting. If the research team includes rare melanoma consumer collaborators (see below), they should also be invited to attend the Milestone Meeting. The Milestone Meeting will be attended by members of the MRP Programmatic Panel, CDMRP staff, the USAMRAA Grants Officer, and other Department of Defense (DOD) stakeholders. Continued funding may be contingent upon the successful completion of specific research milestones and goals.

Other Important Considerations:

Rare Melanoma Consumer Collaborations: For the purposes of the FPA-RM, *a “rare melanoma consumer” is a rare melanoma survivor (active or post-treatment), family member, and/or the caregiver of a rare melanoma survivor who can provide lived experience expertise to the research team.* Applicants to the FPA-RM are encouraged, but not required, to collaborate with the rare melanoma consumer community to maximize the impact and translatability of the research for the benefit of the intended community(ies).

Collaborative research approaches create partnerships between scientific researchers and rare melanoma consumers to create knowledge useable by both sets of stakeholders. Recognizing the strengths of each partner, scientific researchers and rare melanoma consumers collaborate and contribute equitably on all aspects of the project, which may include needs assessment, planning, research intervention design, implementation, evaluation, and dissemination. Collaborative research approaches feature shared responsibility and ownership for the research project to ensure non-tokenistic involvement of the rare melanoma consumers 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 rare melanoma consumer community may be established through integrating rare melanoma consumers into research teams as co-researchers, advisors, and/or consultants. 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 rare 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 rare 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 rare melanoma consumer community.
- The research team assembles a rare melanoma consumer community advisory board. The advisory board may include rare melanoma consumer, a coalition of community-supporting organizations, or any combination thereof that provides advice and consultation throughout the planning and implementation of the overall program and/or individual research projects.

Additional information on collaborative research approaches and the MRP's focus on rare melanomas can be found in:

- Cancer Research UK. Patient involvement toolkit for researchers. <https://www.cancerresearchuk.org/funding-for-researchers/patient-involvement-toolkit-for-researchers>.
- Congressionally Directed Medical Research Programs. The Melanoma Research Program's Renewed Focus on Rare Melanomas and a New Funding Opportunity. https://cdmrp.health.mil/mrp/research_highlights/22RenewedFocusRareMelanomas_highlight.
- 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](https://doi.org/10.2217/fon-2020-1198). Epub 2021 Jul 2. PMID: [34213358](https://pubmed.ncbi.nlm.nih.gov/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](https://doi.org/10.1158/0008-5472.CAN-18-1600).
- Food and Drug Administration (FDA). Center for Drug Evaluation and Research 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 other 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, U.S Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families.
- Explanation of how the project addresses an aspect of melanoma that has relevance or is unique to Service Members, Veterans, and/or their Families.

If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [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 allowed.

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 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 and meets the intent of the FPA-RM.

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

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

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

Funding Details:

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 MRP Focused Program Award – Rare Melanomas should not exceed **\$2,000,000**. 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 \$6.4M to fund approximately two Focused Program Award – Rare Melanomas 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

To be named as the PI on the application, the PI must be an independent investigator at or above the level of Associate Professor (or equivalent).

- The PI is required to devote a minimum of 10% effort to this award.

- An investigator may be named as the PI on only one FY24 MRP FPA-RM application.

The Project Leader(s) for the complementary and synergistic research project(s) must be an independent investigator at or above the level of Assistant Professor (or equivalent).

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

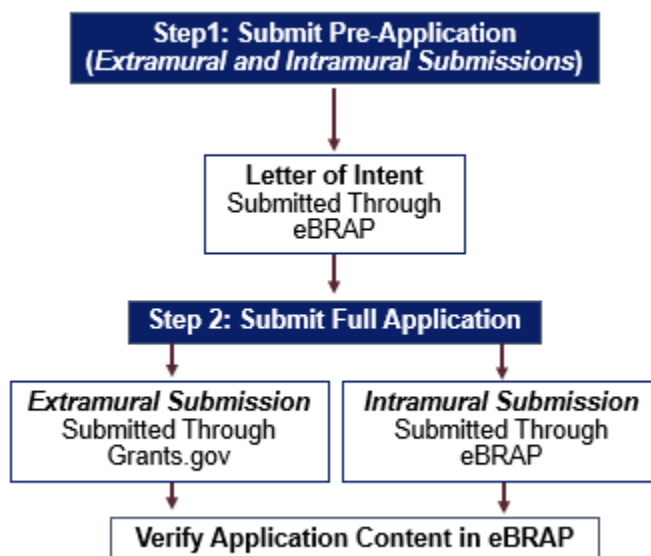
Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission 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 HT942524MRPFARM 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 HT942524MRPFARM from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

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

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

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

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

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

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

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

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

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

When starting the pre-application, applicants will be asked to select a “Mechanism Option”. Please be sure to select the correct option appropriate to your pre-application:

Proposed Research:	Select Option:
DOES NOT include a clinical trial	Focused Program Award – Rare Melanomas
DOES include a clinical trial	Focused Program Award – Rare Melanomas - Clinical Trial Option

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 overarching question and the research projects that will address the question. Identify the Project Leader(s) and any [rare melanoma consumer collaborators](#) (not required) that will serve as an advisor/consultant for the research efforts.

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 include rare 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 rare 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

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 (25-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.

Overall Program: Provide a *brief* summary of the comprehensive effort. Applicants should propose at least two, but no more than three research projects that address a critical unmet need relevant to rare melanoma research and/or patient care. Summarize the areas of synergy across the proposed research projects. A *detailed* description of the Overarching Question and each investigator’s roles and responsibilities will be included in [Attachment 6, Overarching Question Statement](#).

Research Plan: Provide the following details for each proposed research project, organizing each project clearly and separately. *Start each research project on a new page.*

- **Title:** Provide a title for each research project.
- **Project Leader:** Identify the Project Leader and any key personnel, as appropriate.
- **Background:** Present the scientific rationale to support the proposed research project and its feasibility, as established through the demonstration of logical reasoning and a critical review and analysis of published literature; include relevant literature citations. As appropriate for the proposed research project, provide sufficient preliminary data to support the feasibility of work proposed. A research project proposing a clinical trial *must* include sufficient preliminary data to justify the conduct of the trial. Any unpublished, preliminary data provided should originate from the laboratory of the Project Leader or a member of the research team.
- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective to be reached.
- **Specific Aims:** State the specific aims of the research project. *Only present 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.
 - **Statistical considerations for research projects that DO NOT propose a clinical trial:** If applicable, clearly describe the statistical plan and the rationale for the

statistical methodology. Describe an appropriate power analysis, how it supports the sample size, and how it adequately represents an assessment of the population or subpopulation proposed. 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.

- ***Statistical considerations for research projects that DO propose a clinical trial:*** Describe the statistical model and data analysis plan with respect to the trial objectives. Specify the approximate number of human participants to be enrolled. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and any proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
- If cell lines are to be used, justify why the proposed cell line(s) were chosen 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 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.
- If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human participants will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of participants, and for acquiring any additional research resources necessary for conducting the proposed research project. 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 the PI, one of the Project Leaders, or key personnel on the 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 research projects that propose ***clinical research and/or a clinical trial***, 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/participants. 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. See [Attachment 2](#) for instructions regarding the Inclusion Enrollment Report that is required with all applications that propose clinical research/and or a clinical trial.

- For research projects that propose using funds from this award for prospective human participant enrollment, provide a mitigation plan for the estimated attrition of subjects.
 - 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.
- **Clinical Trial Information (if applicable):** *For research projects that propose using funds from this award to conduct a clinical trial*, details regarding the Clinical Trial Strategy must be described in [Attachment 10](#). Do not duplicate information from the Clinical Trial Strategy in the Project Narrative. The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested during award negotiations. In the Project Narrative, provide the following information:
- Identify the intervention. Briefly outline the primary – and secondary, if applicable – endpoints of the trial and any relevant biomarkers. A thorough description of the endpoints will be request in [Attachment 10](#).
 - Describe the type of study to be performed (e.g., treatment, prevention, diagnostic), the study phase or class (if applicable), and the study model (e.g., single group, parallel, crossover). Explain how the chosen trial design is best suited to answer the proposed research question.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

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

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

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

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

Letters of Organizational Support (two-page limit per letter is recommended): Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources 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 and/or a clinical trial is proposed): As applicable, *for each research project that proposes clinical research and/or a clinical trial*, 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 (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects):** 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.

Clarity and completeness within the space limits are highly important.

Technical abstracts must be provided for the overall program, as well as each individual research project, with each abstract starting on a new page.

The technical abstract for the *overall program* should be written using the outline below.

- **Overarching Question:** State the overarching question that will be addressed by the research plan and describe how it will address a critical unmet need for the rare melanoma community.
- **Research Team:** Describe the research team assembled by the PI, including how the expertise and resources of each member, including the PI, will combine to create a robust collaboration.
- **Research Plan:** Provide a brief description of the proposed research projects.
- **Impact:** Summarize the potential impact of the proposed effort on the health and well-being of Service Members, Veterans, their Families, and all people impacted by the rare melanoma(s) being studied in the proposed research.

The technical abstract for *each individual research project* should be written using the outline below.

- **Title:** Provide the title of research project.
- **Background:** Present the scientific rationale behind the proposed research project.
- **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.
- **Impact:** Summarize how the proposed research project will make an important contribution for the rare melanoma field(s) being studied.

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 (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects):** Upload as “LayAbs.pdf”. The lay abstract is used by all reviewers, and addresses issues of particular interest to the rare melanoma consumer 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 abstracts.*

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

Lay abstracts must be provided for the overall program, as well as each individual research project, with each abstract starting on a new page.

The lay abstract for the ***overall program*** should address the following elements.

Explain how the proposed effort addresses a critical unmet need relevant to the rare melanoma community.

Describe the overall question to be addressed.

Summarize the ultimate applicability and impact of the research for the rare melanoma consumer community. Include how the proposed research will benefit Service Members, Veterans, their Families, and the American public.

If applicable, summarize the rare melanoma consumer collaboration plan, including the name(s) of the rare melanoma consumer(s) and/or rare melanoma community-serving organization(s) involved in the collaboration.

The lay abstract for ***each individual research project*** should address the following elements.

- Provide the title of the individual research project.
- Summarize the scientific rationale, objective, and aims for ***each*** of the proposed research projects.
- For ***each*** proposed research project, describe the applicability of the research to rare melanoma patients and survivors 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 rare melanoma patient care, outcomes, or survivorship. What is a reasonable expectation for success for the research project? If the research project is too basic for near-term clinical applicability, describe the interim outcomes expected by the end of the period of performance and their applicability to the field of rare melanoma research and/or patient care. Even basic research should have an ultimate goal of advancing the rare melanoma field and/or impacting patient care.

If applicable, summarize the rare melanoma consumer collaboration plan, including the name(s) of the rare melanoma consumer(s) and/or rare melanoma community-serving organization(s) involved in the collaboration.

- **Attachment 5: Statement of Work (seven-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 Focused Program Award - Rare Melanomas, refer to either the “Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work” or “Example: Assembling a Generic Statement of Work”, whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

An individual SOW should be included for the overall program and for each research project. Start each SOW on a new page and ensure the title of the research project is listed. If individual documents are created, combine and upload as a single PDF.

The SOW for the overall program should outline the key milestones and communication plans described in the Implementation Plan.

Each research project SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks related to the major tasks and milestones within the period of performance. *The SOWs should only describe the tasks that would be funded by this award.*

- **Attachment 6: Overarching Question Statement (three-page limit): Upload as “Question.pdf”.**
 - **Overarching Question:** Describe the overarching question to be addressed and justify how it addresses a *critical unmet need relevant to rare melanoma research and/or patient care*. Clearly articulate the rationale for the overarching question; include relevant literature citations as appropriate. Clearly explain how the proposed research projects are not dependent upon each other but are interrelated and multidisciplinary and will address the overarching question in unique but complementary ways. Articulate how the proposed program is synergistic and will advance toward a solution that would not be possible through individual efforts.
 - **Research Team:** Describe how the PI’s research experience, leadership skills, and commitment to making an impact in rare melanoma research and/or patient care demonstrate qualifications necessary to coordinate this collaborative effort. Describe the qualifications of the Project Leader(s) and how those qualifications are appropriate for the completion of the proposed research.

Describe the roles and responsibilities of the PI and each Project Leader, as well as their intellectual contribution to the proposed program. Describe how the overall program depends on each investigator’s unique skills and how the assembled expertise and resources will create a robust, synergistic collaboration necessary to address the overarching question. Provide the time commitment for the PI and each Project Leader and justify that the committed time is appropriate for the completion of the proposed research. The PI is required to devote a minimum of 10% effort to this award.

Include a figure within the three-page limit illustrating the organization of the overall program.

- **Implementation Plan:** Provide an implementation plan for completing the proposed research projects within the proposed period of performance that identifies critical milestones and outlines the knowledge, resources, and/or technical innovations that will be utilized to achieve the stated milestones. Describe how individual research project performance will be assessed during the course of the award, including progression toward defined milestones, realization of study objectives, and success in addressing the overarching question.

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

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

- **Attachment 7: Impact Statement (three-page limit for applications that propose two projects; four-page limit for applications that propose three projects): Upload as “Impact.pdf”.**

Impact statements must be provided for the overall program, as well as each individual research project, with each impact statement starting on a new page. ALL impact statements should be written using language that will be readily understood by readers without a background in science or medicine.

The impact statement for the *overall program* should include the following elements:

- Explain how the overall program will make important scientific advances for the rare melanoma community(ies) affected by the proposed research.
- Explain how the overall program will promote greater understanding of the causes and progression of rare melanomas and/or will promote the development of improvements in prevention, detection, diagnosis, treatment, and/or quality of life for the rare melanoma community.
- Describe a practical long-term vision for how the outcomes from the overall program will impact the lives of rare melanoma patients.

The impact statements for the *individual research projects* should include the following elements:

- Describe how the anticipated research outcome(s) or product(s) resulting from the research project will impact rare melanoma research and/or patient care in the short term.

- Describe the relevance of the research project on the health and well-being of Service Members, Veterans, their Families, and all people impacted by the rare melanoma(s) being studied in the proposed research project.
- For projects that propose a clinical trial, explain how the targeted patient population will benefit from the proposed intervention and how the outcome(s) will ultimately be translated to rare melanoma patients. Explain how the intervention being tested compares with currently available interventions and/or standards of care.
- **Attachment 8: Post-Award Transition Plan (three-page limit): Upload as “Transition.pdf”.** PIs are encouraged to work with their organization’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 program 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 rare melanoma 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 nonfederal 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 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: Rare 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 rare melanoma consumer community.*)
 - **Rare Melanoma Consumer Collaboration Statement (two-page limit is recommended):** Applicants that propose to collaborate with the [rare melanoma consumer community](#) should provide a Rare Melanoma Consumer Collaboration statement that addresses the following:
 - Describe the collaborative research approach that will be used (collaborating with at least one rare melanoma consumer, partnering with a rare melanoma community-supporting organization, etc.), including a justification for the approach.
 - Provide the name of the rare melanoma consumer(s) and their affiliation(s) and/or the name(s) of the community-supporting organization(s) who will provide advice and consultation throughout the planning and implementation of the research project.
 - Indicate the input from the rare melanoma consumer 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 outcomes from the overall program and/or individual research projects.
 - Describe any training that will be provided to either scientific researchers and/or rare melanoma consumer community members on collaborative research approaches, decision-making, and equitable participation.
 - Describe the process measures that will be used to assess the effectiveness of the chosen collaborative research approach.
 - **Letter(s) of Rare Melanoma Consumer Collaboration (two-page limit per letter is recommended):** Provide a letter signed by each rare melanoma consumer collaborator and/or rare melanoma 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 rare melanoma consumer collaborator(s) and describe the relevance of those qualifications to the proposed research.

- **Attachment 10: Clinical Trial Strategy Statement, *if applicable* (no page limit): Upload as “Clinical.pdf”. This attachment is only required for research projects that propose using funds from this award to conduct a clinical trial. If a Clinical Trial Strategy Statement is included with any application that does NOT propose a clinical trial, then the Clinical Trial Strategy Statement will be removed prior to the application being reviewed. Do not duplicate information from the Project Narrative in the Clinical Trial Strategy Statement.**
 - Describe the clinical trial team, including details regarding how the team possesses the appropriate expertise for conducting the proposed trial.
 - Demonstrate the availability of the intervention. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI/Project Leader has obtained access to those rights for conduct of the clinical trial.
 - Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Provide a detailed description of the primary and any secondary or interim endpoints/outcome measures, explain why they were chosen, and describe how and when they will be measured. Outline what measures will be used to minimize bias, including blinding and randomization procedures. Describe any other measures to be taken to reduce bias. Include a description of controls, as appropriate. Outline the timing and procedures planned during the follow-up period. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human participant will experience.
 - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, ***clearly articulate the portions of the study that would be supported with funds from this award.***
 - Provide detailed plans for initiating the clinical trial within the first year of the award period of performance.
 - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
 - **Regulatory Documentation:** For the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any relevant international regulatory agency unless otherwise noted.
 - ***For products/interventions that DO NOT require regulation by a Regulatory Agency:*** Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. No further regulatory documentation is required.
 - ***For products that DO require regulation by a Regulatory Agency:*** If the product is not currently FDA-approved, -licensed, or -cleared, and requires an

Investigational New Drug/Investigational Device Exemption (IND/IDE) or equivalent, provide detailed plans for an FDA IND/IDE application submission within 60 days of the award. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and indication to be tested in the proposed study.

- If available, provide documentation that:
 - ❖ Indicates the date of Regulatory Agency submission, application number, and sponsor for any existing FDA applications in place.
 - ❖ Supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) for the product.
 - ❖ Shows the communication from the FDA indicating the IND or IDE application is active/safe to proceed.

The first page of the statement may include a header identifying the name of the attachment (e.g., “Clinical Trial Strategy”) to aid the review of the application.

- **Attachment 11: 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 12: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) **Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - **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.
- (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 12.

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 **4** years.

The application’s direct costs budgeted for the entire period of performance should not exceed **\$2,000,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

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

- Travel costs for the PI and up to two additional members of the research team to present project information at a 1-day DOD MRP Milestone meeting during year 3 of the period of performance. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Travel costs for one rare melanoma patient consumer collaborator (if included on the research team) to attend the 1-day DOD MRP Milestone meeting.
- Travel in support of multidisciplinary collaborations.

- Costs for up to three investigators to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to disseminate project results from the FY24 MRP FPA-RM.

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:

Scored review criteria for the overall program:

- **Overarching Question and Implementation Plan**
 - To what extent the application describes the overarching question and justifies how it addresses a critical unmet need relevant to the rare melanoma research and/or patient care.
 - To what extent the application clearly articulates the rationale for the overarching question.
 - To what extent the research projects are not dependent upon each other but are interrelated and multidisciplinary, and how well the application articulates that the proposed program is synergistic and will advance toward a solution that would not be possible through individual efforts.
 - To what extent the implementation plan identifies critical milestones and outlines the knowledge, resources, and/or technical innovations that will be utilized to achieve the stated milestones.
 - To what extent the implementation plan describes how individual research project performance will be assessed during the course of the award.
 - To what extent the implementation plan describes plans for communication, decision-making, allocation of resources, coordination of results, and data sharing among all investigators and organizations participating in the overall program.

- **Research Team and Key Personnel**

- To what extent the PI's experience, leadership skills, and commitment to making an impact in rare melanoma research and/or patient care demonstrate qualifications to coordinate the collaborative effort.
- To what extent each Project Leader's qualifications are described and appropriate for the completion of the proposed research.
- To what extent the roles and responsibilities of the PI and each Project Leader are described as well as how their intellectual contributions contribute to the overall program.
- To what extent the overall program depends on the unique skills of each investigator.
- To what extent the assembled expertise and resources will create a robust, synergistic collaboration.
- If applicable, to what extent the composition of the clinical trial team is well-described, including details on how the team possesses the appropriate expertise for conducting the proposed clinical trial.
- Whether the PI will devote a minimum of 10% effort to this award.
- Whether the time commitment of each Project Leader is provided and is appropriate for the completion of the proposed research.
- Whether appropriate letters of support and collaboration indicate that the research team has the support and resources necessary for the proposed research projects and/or clinical trial.
- Based on the biographical sketches, to what extent the Project Leader's and associated key personnel's backgrounds are appropriate to complete the proposed research projects.

- **Post-Award Transition Plan**

- To what extent the post-award transition plan describes the anticipated research outcome(s) and/or product(s).
- To what extent the plan outlines the next logical steps to be taken by the research team upon successful completion of the program to advance the 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 application describes the methods and strategies necessary for the research outcome/product to impact rare melanoma patient care and outcomes, even if

those are long-term goals. Whether the post-award transition 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 of investigation, development, and/or commercialization.
- To what extent the plan assesses 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.
- 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 overall program.

- **Impact**

Assuming success of the overall program, to what extent:

- The overall program will make important scientific advances for the rare melanoma patient community(ies) affected by the proposed research.
- The application describes how the overall program will promote greater understanding of the causes and progression of rare melanomas and/or will promote the development of improvements in prevention, detection, diagnosis, treatment, and/or quality of life for the rare melanoma community.
- The application articulates a long-term vision for how the outcomes from the overall program will impact the lives of rare melanoma patients.

Scored review criteria for each individual research project:

- **Research Strategy and Feasibility**

- To what extent the scientific rationale supports the project and its feasibility, as demonstrated by logical reasoning, a critical review and analysis of the literature, and, as appropriate for the proposed research project, sufficient preliminary data are provided. If a clinical trial is proposed, whether the provided preliminary data justify the conduct of the trial.
- To what extent the hypothesis or objective, experimental design, methodology, and analyses are well-developed and support successful completion of the specific aims within the period of performance of the award.
- To what extent the application acknowledges potential problems and pitfalls and presents alternative methods and/or approaches.

- If applicable, 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 a clinical trial is proposed, to what extent the statistical model and data analysis plan with respect to the trial objectives are well-described and appropriate, and sufficient justification is provided for the proposed number of study participants.
- If applicable, whether the use of the proposed cell lines is justified.
- If applicable, to what extent the proposed animal studies are designed to achieve the research objectives, to include the use of appropriate models.
- If applicable, to what extent the applicant demonstrates the availability of human data sets, human anatomical substances, and/or human subjects, including a detailed plan for the acquisition of samples/resources and/or recruitment of human 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 and/or proposed clinical trial, 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.
- If applicable, to what extent the application describes access to the study population, recruitment plans, and inclusion/exclusion criteria for any projects that propose using funds from this award for prospective human participant enrollment. Whether an appropriate mitigation plan is provided for the estimated attrition of subjects.

- **Impact**

Assuming success of the proposed research project, to what extent:

- The anticipated outcomes/products from each research project will impact rare melanoma research and/or patient care in the short term.
- The proposed research is relevant to the health and well-being of Service Members, Veterans, their Families, and all people impacted by the rare melanoma(s) being studied in the proposed research project.
- If a clinical trial is proposed, the application explains how the targeted patient population(s) will benefit from the proposed intervention.
- If a clinical trial is proposed, the application explains how the outcomes of the proposed trial will be translated to rare melanoma patients.

- **Clinical Trial Strategy** (*only applicable if funds from this award will be used to conduct a clinical trial*)
 - To what extent the intervention is clearly identified, and appropriate endpoints are described.
 - To what extent the application demonstrates availability of the intervention and indicates who holds the intellectual property rights to the intervention.
 - To what extent the clinical trial design is best suited to answer the proposed research question.
 - To what extent the proposed clinical trial methodology and study variables are outlined in sufficient detail to demonstrate a clear course of action and justification. Whether sufficient detail is provided in chronological order for a person uninvolved in the study to understand what the human participant will experience.
 - To what extent the budget clearly justifies how the proposed clinical trial will be supported with funds from this award.
 - If applicable, how well the application describes whether the proposed clinical trial was initiated using other funding prior to this application and whether the portions of the study that would be supported with funds from this award are clearly articulated.
 - Whether the detailed plans for initiating the clinical trial within the first year are feasible.
 - If applicable, to what extent the application describes how data will be reported and how it will be assured that the documentation will support a regulatory filing.
 - To what extent the application includes appropriate plans and/or documentation in support of Regulatory Agency submissions and/or approvals.

The following *unscored criteria* will also contribute to the evaluation of the overall application:

- **Data and Resource Sharing**
 - To what extent the plan for sharing project data and research resources is appropriate and reasonable.
 - If applicable, whether specific repository(ies) are named where scientific data and/or resources arising from the project will be archived.
- **Budget**
 - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

- Whether there may be overlap with existing or pending awards of the PI or Project Leader(s).
- To what extent the budget is appropriate for the scope of the proposed research projects.

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

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

- How well a collaborative research approach with the rare melanoma consumer community is described.
- Whether a rare melanoma consumer(s) and/or a rare melanoma community-supporting organization(s) is named.
- How well application describes the input from the rare melanoma consumer partner(s) that has already been and/or will be captured.
- How well the application describes how the rare melanoma 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 outcomes from the overall program and/or individual research projects.
- Whether a letter (or letters) of support from the rare melanoma consumer collaborator(s) is 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**

- To what degree 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 abstracts and impact statements 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:
 - Adherence to the intent of the Focused Program Award – Rare Melanomas described in [Section II.B](#)
 - Relative impact
 - Program portfolio balance
 - Relevance to military health

II.E.2. Application Review and Selection Process

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

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

II.E.3. Integrity and Performance Information

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

II.F.2. PI Changes and Award Transfers

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 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.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

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.

Award Expiration Transition Plan: 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.

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

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

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

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

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed (e.g., a Clinical Trial Strategy ([Attachment 10](#)) is provided for applications that do not propose conducting a clinical trial).

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 PI or any named Project Leader does not meet the eligibility criteria.
- The applicant organization submits more than one FPA-RM application with the same investigator named as the PI.

- The main subject of the research is non-melanoma skin cancers.
- An application that proposes a clinical trial is missing the Clinical Trial Strategy Statement ([Attachment 10](#)).

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Attachments	
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>
Overarching Question Statement – Attachment 6, upload as “Question.pdf”	<input type="checkbox"/>
Impact Statement – Attachment 7, upload as “Impact.pdf”	<input type="checkbox"/>
Post-Award Transition Plan – Attachment 8, upload as “Transition.pdf”	<input type="checkbox"/>
Rare Melanoma Consumer Collaboration Plan <i>(if applicable)</i> – Attachment 9, upload as “Consumer.pdf”	<input type="checkbox"/>
Clinical Trial Strategy Statement <i>(if applicable)</i> – Attachment 10, upload as “Clinical.pdf”	<input type="checkbox"/>
Representations <i>(Extramural submissions only)</i> – Attachment 11, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 12, upload as “IGBudget.pdf”	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Research & Related Budget <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	<input type="checkbox"/>
Budget <i>(Intramural submissions only)</i>	<input type="checkbox"/>
Include budget justification	<input type="checkbox"/>
Project/Performance Site Location(s) Form	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form <i>(if applicable)</i>	<input type="checkbox"/>

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
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
FDA	Food and Drug Administration
FPA-RM	Focused Program Award – Rare Melanomas
FY	Fiscal Year
IDE	Investigational New Drug
IND	Investigational Device Exemption
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs

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://afri.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/>