Program Announcement for the Department of Defense
Defense Health Program

Melanoma Research Program

Focused Program Award – Rare Melanomas

Funding Opportunity Number: HT942525MRPFPARM

Pre-Application Due: June 30, 2025

Application Due: October 1, 2025

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

Content

Before You Begin

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

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

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

Grants.gov Contact Center

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

Questions regarding Grants.gov registration and Workspace.

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

1. Basic Information About the Funding Opportunity

Summary: Supports a multidisciplinary research program of at least two, but not more than three, distinct but complementary research projects addressing an overarching question relevant to rare melanomas.

Distinctive Features:

- ***New for FY25*** **This funding mechanism is a *partnering* mechanism, requiring an Initiating Principal Investigator (PI) and at least one, but not more than two, Partnering PIs,** see Figure 1.
    - Each named PI is expected to be a Project Leader for one of the proposed research projects. If recommended for funding, each PI will be named on separate awards to the recipient organization(s).
- ***New for FY25*** After submitting the required pre-application, ***investigators must receive an invitation to submit a full application***.
    - Only the Initiating PI will submit a pre-application. All PIs will need to submit full applications. The Partnering PI(s)'s application is an abbreviated package specific to their proposed research project.
- Clinical trials ***are*** allowed.
- Investigators are encouraged, but not required, to form collaborative relationships with the rare melanoma consumer community to maximize the impact and translatability of the research for the benefit of the intended community(ies).

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $6.4 million (M) to fund approximately 2 Focused Program Award – Rare Melanoma applications with combined direct cost caps of $2.0M. The maximum period of performance is 4 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 30, 2025
- **Invitation to Submit an Application:** July 31, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, October 1, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, October 7, 2025
- **Peer Review:** December 2025
- **Programmatic Review:** February 2026

Announcement Type: Initial

Funding Opportunity Number: HT942525MRPFPARM

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

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

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

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

2.1.2. Principal Investigator

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

- The ***Initiating*** PI is required to devote a minimum of 10% effort to this award.
- An investigator may be named as the ***Initiating*** PI on only ***one*** FY25 Melanoma Research Program (MRP) Focused Program Award – Rare Melanomas (FPA-RM) application.

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

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

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

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

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the MRP. Congress initiated the MRP in 2019 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the MRP from FY19 through FY24 totaled $180M. The FY25 appropriation is $40M.

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

Studies involving non-melanoma skin cancers are not allowed under the FY25 MRP.

3.1. Award History

The FPA-RM mechanism was first offered in FY22. Since then, 34 FPA-RM applications were received, and seven were recommended for funding.

3.2. Intent of the Focused Program Award – Rare Melanomas

The FY25 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). ***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.*** Although the FY25 MRP will accept applications addressing topics relevant to uveal melanoma, the MRP is particularly interested in receiving applications that address other uncommon presentations of melanoma, including but not limited to:

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

The FY25 FPA-RM requires more than one PI. One PI will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s) and will be the PI (i.e., Project Leader[s]) responsible for the other proposed research project(s). All PIs should contribute significantly to the development and execution of the proposed research program. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. Be sure to carefully read and follow the instructions in Sections 4.3.1 and 4.3.2 regarding the full application components required of the Initiating PI and Partnering PI(s), respectively. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

3.2.1. Key Elements for the FPA-RM

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

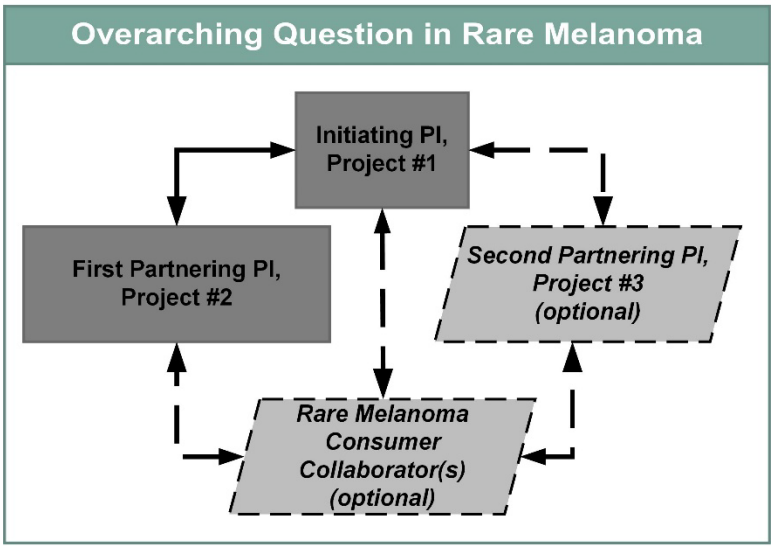


Figure 1. For the FY25 FPA-RM, a research team, consisting of an Initiating PI and one or two Partnering PIs, (i.e., Project Leaders), will engage in at least two, but not more than three, distinct but complementary projects to answer an overarching question relevant to rare melanomas. The research team 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 an Initiating PI with demonstrated success in leading large, focused projects. The Initiating PI is required to devote a minimum of 10% effort to this award and is expected to be the lead for one of the proposed research projects. The Initiating PI should create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team, which includes the Partnering PI(s). The research team assembled by the Initiating PI should be highly qualified and multidisciplinary. The resources and expertise brought to the team by each PI should combine to create a robust collaboration. The Initiating PI and the Partnering PI(s) do not have to be at the same organization.

Research Projects: Applications should include multiple, distinct research projects that are each led by an individual PI 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 be 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 where the***

completion of one project is dependent on the success/completion of the other proposed 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 PIs 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 DOD stakeholders. Continued funding may be contingent upon the successful completion of specific research milestones and goals.

3.2.2. Other Important Considerations for the FPA-RM

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 consumers, 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.
- 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 P.A. 2021. Patient Engagement in Cancer Research From the Patient's Perspective. *Future Oncology* 17(28): 3717-3728. doi: 10.2217/fon-2020-1198. Epub 2021 Jul 2. PMID: 34213358
- Tivey A., Huddar P., Shotton R., et al. Patient Engagement in Melanoma Research: From Bench to Bedside. Future Oncol. 2021 Oct;17(28):3705-3716. doi: 10.2217/fon-2020-1165. Epub 2021 Jul 2. PMID: 34213356.
- Salamone J.M., Lucas W., Brundage S.B., et al. 2018. Promoting Scientist-Advocate Collaborations in Cancer Research: Why and How. *Cancer Research* 78(20): 5723-5728. doi: 10.1158/0008-5472.CAN-18-1600.
- Food and Drug Administration. Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development.

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 the Full Application Submission Components, for detailed information. Refer to the General Application Instructions, Appendix 4, for additional information.

A list of websites that may be useful for identifying additional information about ongoing DOD and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 3 of this document.

Preclinical Research: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, Nature 490:187-191. While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

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. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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

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

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

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

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

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

For more information, a Human Subject Research Resource is available on the CDMRP website.

3.3. CDMRP-wide Encouragements

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

- Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.
- The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.
- A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY25 MRP priorities.

3.4. Funding Instrument

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

3.5. Funding Details

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

Cost Cap: The ***combined*** direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **$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.

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

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

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

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

Must be requested for:

- Travel costs associated with attending a Milestone meeting as described in Section 8.3.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).
- 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 to scientific/technical meetings is to disseminate project results from the FY25 MRP FPA-RM.

4. Application Contents and Format

4.1. Application Overview

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

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

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

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

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

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

  The Preproposal Narrative should provide the information outlined below. NOTE: Recommended character limits do not supersede the maximum two-page limit for the preproposal narrative.

  - Overarching Question (Recommended 2,000-character limit):
    - Describe the overarching question to be investigated and justify how it addresses a critical unmet need relevant to rare melanoma research and/or patient care.
  - Proposed Research Projects (Recommended 1,600 [three projects]- to 2,500 [two projects]-character limit per research project):
    - Provide the titles for at least two, but no more than three, independent research projects. Identify who will be the PI (i.e., Project Leader) for each proposed research project.
    - State the hypothesis to be evaluated/objective to be obtained for each research project and describe the specific aims that will be completed in support of the hypothesis/objective.
    - Summarize how the proposed research projects will address the overarching question in unique but complementary ways. Explain how the completion of any one proposed research project will not depend on the completion of any other proposed research project(s).
    - Describe the anticipated research outcomes or products that the research team expects to result from each proposed research project. Explain how the anticipated outcomes will advance rare melanoma research and/or improve patient care.

- Research Team (Recommended 2,000-character limit):
  - Summarize how the resources and expertise brought to the team by each PI will combine to create a robust collaboration.
- A figure may be included within the two-page limit illustrating the organization of the overall program but it is ***not required***.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **Initiating PI and Partnering PI(s) Biographical Sketches:** ***All PI biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. Biographical sketches for any other key personnel ***should not*** be provided with the pre-application.

4.3. Step 2: Full Application Components

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

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

4.3.1. Full Application Components for the Initiating PI

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

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

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

(b) Attachments:

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

- **Attachment 1: Project Narrative (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. The titles of the research projects should remain unchanged from the pre-application to the full application.
- **Project Leader:** Identify the Partnering PI who will serve as 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 one of the PIs or another member of the FPA-RM 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. If there are sample size limitations (budget limitations, availability of specimens, etc.) justify how analysis of the proposed sample size(s) will yield meaningful information.

- ***Statistical considerations for research projects that DO propose a clinical trial***: Describe the statistical model and data analysis plan with respect to the clinical trial objectives. Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.
- A separate Sex as a Biological Variable (SABV) Strategy is required for each proposed research project as part of Attachment 2.
- 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.
- If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human participants will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of participants, and for acquiring any additional research resources necessary for conducting the proposed research project. For projects that propose using human data sets and/or specimens from biobank(s), biorepository(s), and/or ongoing or completed clinical trial(s), and if the manager or lead investigator is not one of the named PIs or key personnel on the application, applicants should provide letter(s) of collaboration within 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, 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, 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 participants.
- 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: Clinical Trial Strategy Statement. 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 requested 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 Support (two-page limit per letter *is recommended*):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-

ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.

- **SABV Strategy (two-page limit is recommended for each SABV strategy)**: Describe the strategy for how sex will be considered as a biological variable ***for each proposed research project***. Start each SABV strategy on a new page and include the title of the research project to which the strategy applies. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants if applicable. Include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- **Inclusion Enrollment Plan (*only required if clinical research and/or a clinical trial is proposed*):** As applicable, ***for each research project that proposes clinical research and/or a clinical trial***, provide anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Attachment 3: Technical Abstract (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 research project.
- **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.

- **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 affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

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

  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 outcomes 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 of the proposed research project.
- Summarize the applicability of the research to rare melanoma patients and survivors considering the following points.
  - What populations will the proposed research project help?
  - What are the potential clinical applications, benefits, and risks?
  - Summarize the short- and long-term goals that are related to rare melanoma patient care, outcomes, or survivorship.
- 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 eBRAP for the "Suggested SOW Format".

  For the FPA-RM, 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.

  The SOW for each research project 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. Specific research milestones to be accomplished by the end of year two in the period of performance must be clearly defined. ***The SOWs should only describe the tasks that would be funded by this award.***

  Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and each Partnering PI should be clearly noted.

- **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 Initiating 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 Partnering PI(s) and how those qualifications are appropriate for the completion of the proposed research.

  Describe the roles and responsibilities of the Initiating PI and Partnering PI(s), 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 each PI and justify that the committed time is appropriate for the completion of the proposed research. The Initiating 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.

- **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 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.
  - Articulate a practical long-term vision for how the implementation/dissemination of the research outcome(s) and/or intervention(s) from the overall program will make

important scientific advances in rare melanomas, improve patient care and/or improve the quality of life of rare melanoma patients.

The impact statement for ***each individual research project*** should include the following elements:

- Define a reasonable expectation for success for the proposed research project/clinical trial. 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. 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 eventual 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, describe how the anticipated outcomes of the proposed research project will make an impact in understanding health differences between sexes.
- 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 research projects that propose a clinical trial:
  - Describe any relevant controversies, treatment issues, or health disparities that will be addressed by the proposed 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 improves upon currently available interventions and/or standards of care.
  - Describe any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance of the intervention by users.

- **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:
  - Define the overall program'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. Assess 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.

- **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 for any research project 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.**
  - Provide the title of the research project with which the clinical trial is associated. If multiple research projects will support clinical trials, then start each clinical trial strategy on a new page.
  - Describe the composition of the clinical trial team in enough detail to determine whether the team includes relevant subject matter expertise to accomplish the proposed clinical trial. Include any external consultants or advisors who will provide critical guidance and input to the clinical trial team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
  - Demonstrate the availability of the intervention. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation demonstrating the clinical trial team's access to the intervention(s) for the duration of the clinical trial.
  - Describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Describe the recruitment process in detail, including methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
  - Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations for what study participants will experience. 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 study 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 clinical trial 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 U.S. Food and Drug Administration (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. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. 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.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

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

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

Initiating and Partnering PIs must have a separate budget and justification specific to their effort towards the overall program and proposed research project that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI(s) even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf".

4.3.2. Full Application Components for each Partnering PI

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

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

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

(b) Attachments:

- **Attachment 5: Statement of Work (seven-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

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

Initiating and Partnering PIs must have a separate budget and justification specific to their effort towards the overall program and proposed research project that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI(s) should not include budget information for the

Initiating PI, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

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

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

4.4. Other Application Elements

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

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525MRPFPARM from Grants.gov or eBRAP, depending on which submission portal will be used.

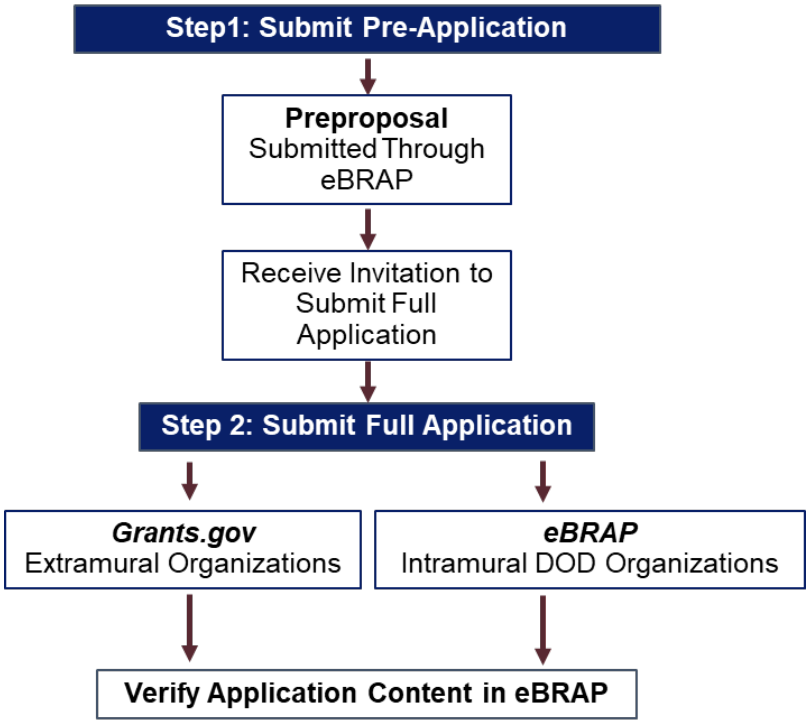
5.2. Unique Entity Identifier and System for Award Management

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

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. Pre-Application Submission

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

NOTE: For applications including rare melanoma consumer collaborator(s), those individuals should be named during the pre-application submission. For administrative purposes, select "Consumer" when assigning the melanoma consumer collaborator(s)'s roles in eBRAP under "Collaborators and Key Personnel".

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.

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

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

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

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

Application Includes:	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**

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

5.3.2. Full Application Submission

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

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application

Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

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

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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

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

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

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

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

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

- To what extent the described overarching question addresses a critical unmet need relevant to rare melanoma research and/or patient care.
- To what extent the two or three proposed research projects will address the overarching question in unique but complementary ways. Whether the completion of any one proposed research project will not depend on the completion of any other proposed research project(s).
- To what extent the anticipated research outcomes or products are appropriate for the proposed research projects and the overarching question being addressed.
- To what extent the Initiating PI is qualified to lead and coordinate this collaborative effort.
- To what extent the qualifications of the Initiating and Partnering PIs are appropriate for the completion of their proposed research projects.

6.2.2. Peer Review Criteria

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

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 Initiating 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 the Partnering PI(s)'s qualifications are described and appropriate for the completion of the proposed research.
  - To what extent the roles and responsibilities of each PI 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 includes relevant subject matter expertise to accomplish the proposed clinical trial.
  - Whether the Initiating PI will devote a minimum of 10% effort to this award.
  - Whether the time commitment of each Partnering PI 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 Partnering PI(s) and associated key personnel's backgrounds are appropriate to complete their respective research projects.

- **Post-Award Transition Plan**
  - To what extent the post-award transition plan defines 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 practical long-term vision for how the implementation/dissemination of the research outcome(s) and/or intervention(s) from the overall program will make important scientific advances in rare melanomas, improve patient care and/or improve the quality of life 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.
  - 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.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single sex study is sufficiently strong.
  - 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, racial, and ethnic group, and an accompanying rationale for the selection of specimens/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:
  - Reasonable expectations for success for the proposed research project/clinical trial are defined.

- The anticipated outcomes/products from each research project will impact rare melanoma research and/or patient care in the short term.
- If applicable, the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- 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 describes any relevant controversies, treatment issues, or health disparities that will be addressed by the proposed clinical trial.
  - The application explains how the targeted patient population(s) will benefit from the proposed intervention and how the intervention being tested improves upon currently available interventions and/or standards of care.
  - The application describes any potential challenges that might limit the impact of the proposed clinical trial, including barriers to implementation or acceptance of the intervention by users.

- **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 clinical trial team includes relevant subject matter expertise to accomplish the proposed clinical trial, including any external consultants or advisors who will provide critical guidance and input to the clinical trial team. Whether the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.
  - To what extent the study population and inclusion/exclusion criteria are well-described. To what extent the recruitment process and barriers to participation are described in detail.
  - 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:

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

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.
  - Whether the lay abstracts and impact statements are written with clarity for persons without a background in science or medicine.

6.2.3. Programmatic Review

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

- Ratings and evaluations of the peer reviewers.
- Relevance to the priorities of the FY25 MRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity.
  - Relative impact.
  - Program portfolio balance.
  - Relative relevance to military health.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

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

6.3.2. Full Application

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to

be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

6.4. Risk, Integrity, and Performance Information

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

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

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

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the MRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

8. Post-Award Requirements

8.1. Administrative and National Policy Requirements

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

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

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

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

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

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

Funded clinical trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded Applicable Clinical Trials to register on ClinicalTrials.gov. Additional data reporting requirements will also apply to Applicable Clinical Trials supported under this funding opportunity. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

8.2. Reporting

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

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

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report. 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 ***(Required for research proposing clinical research and/or clinical trials)***: Enrollment reporting on the basis of sex, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

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

8.3. Additional Requirements

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

Changes in Partnering PI are discouraged, but will be considered under extenuating circumstances that will be evaluated on a case-by-case basis.

The organizational transfer of an award NOT supporting a clinical will be allowed 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.

The Initiating PI and up to two additional members of the research team will be required to present their progress toward accomplishing research milestones at a Milestone Meeting during year 3 of the period of performance. If the research team includes rare melanoma consumer collaborators, then up to one consumer collaborator may also be invited to attend the Milestone Meeting. The meeting will be held in the National Capital Region or virtually, at the discretion of the government.

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

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

9. Other Information

9.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code CD25_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Preproposal Narrative is missing.

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

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative is missing.
- Budget is missing.

9.2.2. Modification

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

9.2.3. Withdrawal

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

- A member of the FY25 MRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP Website.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- The Initiating PI or Partnering PI(s) do not meet the eligibility criteria.
- The applicant organization submits more than one FPA-RM application with the same investigator named as the Initiating 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.
- Failure to submit all associated Initiating and Partnering PI applications by the deadline.

9.2.4. Withhold

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

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Overarching Question Statement – Attachment 6, upload as "Question.pdf"	☐	
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐	
Post-Award Transition Plan – Attachment 8, upload as "Transition.pdf"	☐	
Rare Melanoma Consumer Collaboration Plan (if applicable) – Attachment 9, upload as "Consumer.pdf"	☐	
Clinical Trial Strategy Statement (if applicable) – Attachment 10, upload as "Clinical.pdf"	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch" for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐	☐
Budget **Include Budget Justification**	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable*)	☐	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FPA-RM	Focused Program Award – Rare Melanomas
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational New Drug
IND	Investigational Device Exemption
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
MRP	Melanoma Research Program
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OUSD R&E	Office of the Under Secretary of Defense for Research and Engineering
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SABV	Sex as a Biological Variable
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
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 3. DOD and VA Websites

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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