<u>FY24 Melanoma Research Program Funding Opportunity Frequently Asked</u> Questions

The information provided within this Frequently Asked Questions, FAQ, document is meant to supplement the FY24 Melanoma Research Program, MRP, funding opportunities and General Application Instructions. The FY24 MRP funding opportunities and associated General Application Instructions can be found at the following three locations:

- eBRAP.org, https://ebrap.org/eBRAP/public/ProgramFY.htm?programFYId=589105
- grants.gov, https://grants.gov/search-grants; use "MRP" in the Keyword(s) search
- CDMRP website, https://cdmrp.health.mil/funding/mrp

Eligibility Questions

Is there someone I can ask specific questions about my eligibility status?

No, CDMRP does not provide one-on-one guidance regarding a Principal Investigator's, PI's, eligibility for a specific funding opportunity. All information that PIs require to determine their eligibility status is provided within <u>Section II.C. Eligibility Information</u> of the funding opportunity and within the General Application Instructions. This ensures that all applicants receive the same information. **The MRP funding opportunities intentionally have broadly defined eligibility requirements due to the heterogeneity of investigator's titles across departments and organizations.** Therefore, it is the responsibility of the PI to carefully read the funding opportunity and General Application Instructions and ensure that the appropriate application components, e.g., letter(s) of support, eligibility statement, biosketch, address the eligibility requirements described in the specific funding opportunity. **The PI's responsiveness to the eligibility criteria will be assessed during the two-tiered review process.**

Will applying to an FY24 MRP funding opportunity affect my Early Stage Investigator status on National Institutes of Health, NIH, applications?

CDMRP personnel are not able to answer this question. Investigators should reach out to an appropriate NIH Program Officer/Program Director with questions regarding NIH eligibility requirements.

I am currently a PI, partnering PI, or co-investigator on an active MRP-funded award from a previous fiscal year. Can I apply to one or more FY24 MRP funding opportunity(ies)? Yes, unless specifically restricted in the funding opportunity, investigators who currently have an active MRP-funded award may apply to the FY24 MRP funding opportunities, as long as the proposed research does not overlap with the active award. In other words, the same studies are not proposed in both the active award and FY24 application, the new submission meets the intent of the FY24 funding opportunity and the PI and organization meet the eligibility requirements stated in the funding opportunity.

I am an investigator at a commercial organization, e.g., pharmaceutical company, biotech company, or other for-profit organization. Am I eligible to apply?

Yes, investigators from commercial organizations can apply as long as both the organization and PI meet the eligibility criteria described in the funding opportunity and General Applications Instructions. Additionally, the organization must be able to complete the full application submission process, as described in the General Application Instructions.

It is important to note that there are multiple criteria described in the General Application Instructions that an organization must meet and/or complete before the organization/PI may submit an application. Once of the most time consuming of these items, if it is not already done, is completion of the

Grants.gov registration process. This includes registering the organization as an Entity in the System for Award Management, SAM, and receiving confirmation of an "Active" status. Organizations should allow a minimum of 8 weeks for the completion of the Grants.gov registration process.

My organization does not use job titles such as Assistant Professor, etc. How do I know if I am eligible for a particular funding opportunity?

The CDMRP does not follow the National Institutes of Health guidelines for role designation of project participants. Unless otherwise noted in the funding opportunity, investigators should assign the role of each participant in accordance with the participant's respective involvement in the project. The PI should carefully read the funding opportunity and General Application Instructions and ensure that the appropriate application components—letter(s) of support, eligibility statement, biosketch, etc.—address the eligibility requirements described in the specific funding opportunity. The PI's responsiveness to the eligibility criteria will be assessed during the two-tiered review process. For the purposes of the FY24 MRP funding opportunities, an Independent Investigator is defined as an investigator who is beyond the mentored stage(s) of their career by the full application submission deadline; graduate students, postdoctoral fellows, and clinical fellows are not considered Independent Investigators for the FY24 MRP funding opportunities.

I am an investigator at a foreign organization, i.e., an organization outside of the United States. Am I eligible to apply?

Yes, investigators from foreign organizations are eligible to apply if both the organization and the PI meet the eligibility criteria described in the funding opportunity and General Applications Instructions. The same PI eligibility criteria apply to all investigators, independent of whether they are from domestic or foreign organizations. *All applications* to a particular funding opportunity are held to the same review criteria and partnership with a U.S. organization/investigator is neither required nor a review criterion.

It is important to note that there are multiple criteria described in the General Application Instructions that an organization must meet and/or complete before the organization/PI may submit an application. Once of the most time consuming of these items, if it is not already done, is completion of the Grants.gov registration process. This includes registering the organization as an Entity in the System for Award Management, SAM, and receiving confirmation of an "Active" status. Organizations should allow a minimum of 8 weeks for the completion of the Grants.gov registration process.

General Application Questions and Program Information

Is there a limit to how many applications I am allowed to submit to the FY24 MRP?

Except for the FY24 MRP Focused Program Award – Rare Melanomas, FPA-RM, there are no limits to how many applications an investigator may submit to the MRP as long as each application describes a scientifically distinct project. For the FY24 FPA-RM, an investigator may be named as the Principal Investigator, PI, for only **one** FPA-RM application.

Investigators should note that submission of the same research project to different funding opportunities within the same program and fiscal year may result in the administrative withdrawal of at least one of the duplicative applications.

Do I need to wait for an invitation before submitting a full application to the FY24 MRP?

No, all FY24 MRP funding opportunities, including the FY24 MRP Idea Award, utilize a Letter of Intent, LOI, for the pre-application. An invitation to submit a full application is NOT provided after LOI submission. However, submission of a LOI no later than the FY24 pre-application deadline is required prior to full application submission. LOIs are used for program planning purposes only, e.g., reviewer

recruitment, and will not be reviewed during either peer or programmatic review.

Is there someone I can speak with to discuss whether my research is appropriate for the MRP and/or a specific funding opportunity?

No, CDMRP does not provide one-on-one guidance regarding the suitability of a research project for the MRP or any specific funding opportunity. Additionally, it is not CDMRP practice to provide investigators guidance as to which funding opportunity is best for their career stage and/or proposed research. All information regarding the MRP's strategic goals, Focus Areas, and the intent of the specific funding opportunity are provided within each funding opportunity. This practice ensures open and fair competition and that all applicants receive the same information. Investigators should read <u>Section II.A Program Description</u> and <u>Section II.B. Award Information</u> carefully to understand the FY24 MRP program priorities and the intent of each funding opportunity, respectively, and use this information to guide their application writing and submission.

I submitted an application to an FY24 MRP funding opportunity. When will I receive feedback about my application? When will I be notified of its funding status?

Once an application is submitted, investigators will not receive any intermediate status updates during the two-tiered review process. Rather, investigators will receive both the peer review Summary Statement—the comprehensive written evaluation of the application's strengths and weaknesses—and the funding notification letter approximately 3-6 weeks after the Programmatic Review meeting. The PI and the business official will receive an email notification when these items are available in eBRAP. Additional information about the two-tiered review process can be found at https://cdmrp.health.mil/about/2tierRevProcess.

If my application is not recommended for funding, can I address reviewer comments and resubmit?

The CDMRP does not have a formal resubmission process. However, the PI is free to review the reviewer comments outlined in the summary statement, address comments as they see fit in an updated application and submit a new application to a future funding opportunity. Any future submission will be treated as an entirely new application. It is important for the PI to ensure that the subsequent application meets the requirements and intent of the future fiscal year's funding opportunity. There may be changes in the funding opportunities from one year to the next, even if the name of the funding opportunity remains the same.

If the PI does choose to update a previous fiscal year's application and submit to an FY24 funding opportunity, it is not necessary to call out how the FY24 application addresses critiques from any previous application's review. The CDMRP, and therefore the MRP, does not have standing peer review panels, so the FY24 application will be assigned different reviewers. The reviewers of the FY24 application will have no knowledge or access to previous year(s)'s applications and/or summary statements.

Where can I find information about MRP funding statistics?

Information about how many compliant applications were received and recommended for funding for the FY23 MRP funding opportunities can be found in the "FY23 MRP Information Paper" available at, https://cdmrp.health.mil/mrp/awards/awards. Although each funding opportunity provides an estimate for how many applications the MRP anticipates funding in FY24, the actual number of applications recommended for funding is based on the number and quality of the compliant applications received. The anticipated number of each funding opportunity that the MRP anticipates funding may change from one FY to the next.

Where can I find information about research previously funded by the MRP?

The Technical and Lay Abstracts from all CDMRP-funded research can be viewed at, https://cdmrp.health.mil/search.aspx. The awards can be searched by program, fiscal year, and other parameters. Keep in mind that award information is not available online until after the end of the fiscal year, 30 September, when all award negotiations are completed. Note that it is not recommended that investigators use this information to dissuade themselves from applying to current MRP funding opportunities. In other words, just because an investigator sees funded research that sounds similar to their own does not automatically mean their own application will be less successful.

Before the abstracts, etc. are available at the end of the fiscal year, investigators can find lists of recent applications (institutions and PIs) recommended for funding at, https://cdmrp.health.mil/mrp/awards/awards. However, these lists are not updated after award negotiations are completed and may not reflect changes that occur during negotiations.

Funding Opportunity-Specific Questions

I am interested in applying to the FY24 Melanoma Academy Scholar Award. Are there restrictions as to who can be the Career Guide named in my application?

Yes, the full list of eligibility criteria for the named Career Guide are listed in section <u>II.C.1. Eligible Applicants</u> of the FY24 Melanoma Academy Scholar Award funding opportunity. The named Career Guide **must not be:** the current Director or Deputy Director of the Melanoma Academy, https://cdmrp.health.mil/mrp/

<u>research highlights/22Davies Fisher Holder Chua highlight;</u> named as Career Guide on any previously funded Melanoma Academy Scholar Award applications; or named on more than one FY24 Melanoma Academy Scholar Award application.

However, there are no restrictions regarding the physical location of the Scholar, i.e., the PI, and the Career Guide; the Scholar and Career Guide *do not* have to be located at the same organization.

Is preliminary data truly discouraged for the Idea Award?

Yes, preliminary data is discouraged for the FY24 MRP Idea Award because the intent of the funding opportunity is to spark innovation and generate *novel* research avenues in the melanoma field. The inclusion of preliminary data other than serendipitous findings is not consistent with the exploratory/innovative nature of this award. If preliminary data are included, they should be unanticipated outcomes or results from an unrelated project or study. The Idea Award is NOT intended to expand or extend previously published findings or continue a line of research already established and/or funded in a Pl's laboratory.

Do the FY24 MRP funding opportunities define "rare melanoma"?

No, the FY24 MRP funding opportunities do not provide a definition of rare melanoma because there is no commonly accepted definition for what constitutes a rare melanoma. The FY24 MRP funding opportunities do provide *examples* of relevant rare melanomas, such as uveal, acral, mucosal, pediatric melanomas, but this list is not meant to be all-inclusive. Ultimately, it is up to the investigator to compose their applications to adequately articulate how the proposed research meets the intent of the Focus Area and/or funding opportunity. The application's adherence to the intent of the Focus Area and/or funding opportunity will be assessed during review.

Melanoma Consumer Collaboration Questions

For which funding opportunities are investigators encouraged or required to include collaborations with melanoma consumers?

Collaboration with melanoma consumers is **encouraged**, but not required, in applications to the FY24 Team Science Award and FY24 Focused Program Award-Rare Melanomas.

Collaboration with melanoma consumers is *required* in applications to the FY24 Survivorship Research Award.

What is the definition of a "melanoma consumer"?

For the purposes of the FY24 MRP Team Science Award and the FY24 Survivorship Research Award a melanoma consumer is a melanoma survivor, active or post-treatment, family member, and/or caregiver who can provide melanoma lived experience expertise.

For the purposes of the FY24 Focused Program Award-Rare Melanomas 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 *rare melanoma* lived experience expertise to the research team.

I do basic or preclinical research. How can a melanoma consumer be meaningfully integrated into my research team?

Even if the proposed research is too basic for short-term clinical applicability, MRP-funded basic/preclinical research is expected have the long-term goal of advancing the melanoma field and/or impacting patient care. Keeping this in mind, there are many ways that melanoma consumers could be meaningfully incorporated throughout the duration of a research project, including in research that may be more basic or preclinical in nature. Some examples of collaborative research approaches include incorporating a melanoma consumer within the research team to help identify research questions that have relevance to melanoma survivors and/or their caregivers, introduce investigators to melanoma community-supporting organizations, present research results to patients, etc.

Where can I find additional information and resources for establishing collaborative research approaches with melanoma consumers?

<u>Section II.B Award Information</u> in the FY24 MRP Team Science Award, Focused Program Award-Rare Melanomas, and Survivorship Research Award provide additional information about the intent of establishing collaborative research approaches and include the following list of resources that investigators are encouraged to explore; this is not an exhaustive list:

- Cancer Research UK. Patient involvement toolkit for researchers.
 <u>https://www.cancerresearchuk.org/funding-for-researchers/patient-involvement-toolkit-for-researchers</u>.
- Spears PA. 2021. Patient engagement in cancer research from the patient's perspective. Future Oncology 17(28):3717-3728. doi: 10.2217/fon-2020-1198. Epub 2021 Jul 2. PMID: 34213358
- Salamone JM, Lucas W, Brundage SB, et al. 2018. Promoting scientist-advocate collaborations in cancer research: Why and how. Cancer Research 78(20):5723-5728. doi: 10.1158/0008-5472.CAN-18-1600.
- Food and Drug Administration. Center for Drug Evaluation and Research (CDER) Patient-Focused Drug Development. https://www.fda.gov/drugs/development-approval-process-drugs/cder-patient-focused-drug-development.

Need additional assistance?

- Requests for technical assistance related to LOI or intramural application submissions should be directed to the eBRAP Help Desk, help@eBRAP.org.
- Questions regarding Grants.gov registration and Workspace should be directed to support@grants.gov.
- General questions about the MRP or the FY24 MRP funding opportunities may be directed to usarmy.detrick.medcom-cdmrp.mbx.cdmrp-mrp@health.mil.

List of Acronyms

CDMRP – Congressionally Directed Medical Research Programs
FAQ – Frequently Asked Questions
FY – Fiscal Year
LOI – Letter of Intent
MRP – Melanoma Research Program
NIH – National Institutes of Health
PI – Principal Investigator