

## **New Funding Opportunity: MRA's Next Steps Program**

Since 2007, MRA has awarded \$162 million to support more than 475 research projects led by scientists and clinicians across the globe in 19 countries. MRA will continue to release its annual Request for Proposals (RFPs) each year in August to support research across the different existing grant mechanisms including Team Science, Young Investigator, Pilot, Established Investigator and Dermatology awards.

MRA is excited to announce a new funding opportunity called **Next Steps**, a separate and distinct grant mechanism from the MRA's annual RFP call for applications. The intent of this research funding strategy is to help advance translation of discoveries into the clinic by supporting: 1) needed preclinical resources and tools for the research community to identify and begin to develop new therapies and 2) infrastructural support to analyze and build large datasets and/or develop associated technologies for better detection, diagnosis, treatment, and management of melanoma. Overall, the Next Steps program will secure data necessary to strengthen research proposals for future submission to MRA and other funding agencies.

**Separate Requests for Application (RFAs) in the following three high priority research areas will be released throughout 2024:**

- **Advancing Drug Discovery to Identify New Therapies:** Drug discovery efforts against validated targets to support new therapeutic entity identification, optimization and testing in preclinical models, with an emphasis on targets including adapter proteins, transcription factors, cell surface proteins, etc (ie: CRKL, TERT, GAB2, YAP, LZTR, B7H3);
- **Melanoma Biomarker Development:** Support the analysis or validation of large datasets and/or development of technologies to advance improvements in early detection and diagnosis across different skin types and identify predictive and prognostic biomarkers at different stages of the disease;
- **Characterization of Rare Melanoma Preclinical Models:** Characterization of rare melanoma cell lines and PDX models with different molecular assays and drug sensitivity tests with the goal of making the models and corresponding data available to the research community to enable more preclinical research in rare melanomas.

Awards through the Next Steps Program will be granted as milestone-based payments. Therefore, submitted applications will require the research proposal and budget, and a clearly defined milestone plan and timeline. Funding levels range from \$50,000- \$250,000 (specified in each Next Step priority area announcement) with study duration of 1-2 years. **Only researchers from academic medical centers and universities are eligible to apply including institutions in the U.S. and worldwide.**

Announcements of this program will be made via email and on the MRA website. If you have any questions please contact Joan Levy, MRA Chief Science Officer at [jlevy@curemelanoma.org](mailto:jlevy@curemelanoma.org).

## **Next Steps Program RFA: Priority Area Announcement Melanoma Biomarker Development**

### **Background:**

In 2024, an estimated 100,640 new cases of invasive melanoma will be diagnosed in the U.S. with approximately 8,290 deaths resulting from this disease. Deaths due to melanoma have decreased by about 1% per year during 2017 - 2021, primarily due to the effectiveness of advances in the treatment of melanoma from targeted and immunotherapies. However, despite this progress, approximately 50% of patients either do not respond to existing therapies or ultimately progress through treatment. If detected early, when melanoma is localized, the five-year survival rate is 98.4%. Within the period of 2013-2019, melanoma survival was 94% among Whites but only 71% in Black Americans demonstrating that disparities in survival exist. Furthermore, patients with rare melanoma sub-types (acral, mucosal and uveal melanomas) are usually diagnosed at a more advanced stage of disease as they can be difficult to accurately detect and diagnose. All of this information points to the critical need of identifying biomarkers and/or developing technologies to: 1) more accurately detect all sub-types of melanoma earlier in disease onset and across different skin types; 2) assist in risk stratification to determine which patients are more likely to progress on treatment or need additional types of treatment (ie: adjuvant therapy) which will aid in the management of disease; and 3) identify predictive markers that better match patients to particular therapies thereby offering more precision-based medicine approaches.

To assist in the identification and validation of biomarkers and development of associated technologies, robust and well annotated datasets are essential. Therefore, resources are generally needed to clinically annotate biospecimens and/or images, harmonize datasets across multiple institutions, as well as retrieve additional datasets that will provide useful and more comprehensive information. Generally, funding for this type of infrastructural support is not included in many types of grant mechanisms. In addition, small pilot studies (demonstration studies) may need to be performed to determine that a particular approach or technology for biomarker identification/validation is feasible. **The goal of this Next Step RFA is to provide seed funding to support early research efforts to ultimately identify and/or validate diagnostic, prognostic, or predictive biomarkers or technologies for melanoma detection, treatment, and management of disease. This funding mechanism is intended to lead to well-developed hypothesis-driven research proposals with enough preliminary data for future grant submission to MRA and other funding sources.**

### **Funding Priorities and Pertinent Accompanying Information:**

#### **For this RFA the types of biomarkers to explore include:**

- New technologies and/or diagnostic biomarkers to improve early and more accurate detection of melanoma especially across different skin types;
- Prognostic biomarkers to identify patients who are at higher risk of disease progression or recurrence;
- Biomarkers to predict which patients are more likely to respond to a particular therapy.

**The RFA is seed funding to support:**

- Infrastructural needs to develop well annotated datasets needed for biomarker identification and validation;
- Harmonization of data sets across multiple institutions to add statistical power for biomarker analysis or technology development;
- Optimization studies (e.g. pilot studies or demonstration projects) to validate technology that will improve detection, diagnosis, treatment and/or management of disease.

**Please note the following:**

- Proposals that have a strong hypothesis and preliminary data should consider applying for funding through other mechanisms (ie: MRA annual RFP to be released in August 2024, NIH or other foundations)

**Application Process:**

**Step 1: Letter of Intent**

A one-page letter of intent **must** be uploaded into OneDrive using this link; [Letter of Intent Next Steps Award Melanoma Biomarker Development](#) **no later than July 31, 2024 by 11:59 PM EST**. This LOI is used for administrative purposes and will not be peer reviewed. If MRA identifies any administrative issues, **we will notify you by August 6<sup>th</sup> the latest. If we have not received a LOI by the July 31<sup>st</sup> deadline, you will not be eligible to submit a full application.**

**Step 2: Full applications**

If you have not been contacted by MRA, a full application should be submitted through Proposal Central using this [link](#) and is due on **September 5, 2024 by 11:59 PM EST**. We **WILL NOT** accept any late applications past this deadline so please make sure you allow yourself enough time to receive the required institutional review and approvals for submission. **Please note that access to Proposal Central will not be available until the week of July 8<sup>th</sup>.**

**Award Duration:**

1-2 years

**Funding Level:**

Up to \$150,000 depending on the scope of the research project.

**Payment Schedule:**

Payments will be released after achieving specific milestone accomplishments clearly outlined in a milestone/timeline plan to be included as part of the application. Payments will be approved after MRA's review of progress and determination that milestones and timelines have been met, at MRA's sole discretion. An initial payment will be released upon full execution of the grant contract.

**Eligibility:**

Researchers and clinicians within or outside the U.S. working in academic medical centers and universities or other non-profit research institutions are eligible to apply. Applications will **not** be accepted from for-profit companies.

General eligibility requirements:

- **MRA encourages applications from a diverse pool of investigators with respect to race, gender, sexual orientation, ethnicity, national origin, and disability.** MRA recognizes that diversity in the biomedical research workforce is critical for ensuring that the most creative minds have the opportunity to contribute to realizing our research goals and to ensuring more equitable health outcomes for all.
- **Principal Investigators (PIs) must hold a full-time faculty appointment at the level of Assistant Professor (or equivalent) or above. Early-stage career investigators are encouraged to consider this funding opportunity to compile datasets and/or generate preliminary data that will be useful in applying for additional funding through other sources and aid in their research career development.**
- Fellows/post-docs or those in other training or research support positions are **not** eligible to apply as a PI.
- Individuals employed by state or federal government agencies may reach out to Joan Levy, MRA Chief Science Officer ([jlevy@curemelanoma.org](mailto:jlevy@curemelanoma.org)) to determine their eligibility.
- **An investigator may serve as PI on only one awarded proposal to the Next Steps RFA call in any given calendar year but can serve as a co-Investigator on another proposal in the same calendar year.**
- Multiple applications will be accepted from a single institution, provided that each application has a different PI and represents a distinct project.
- Researchers who have not received prior MRA awards but who have projects that fit within the scope of this RFA are eligible to apply.

If there are any questions about eligibility, please contact Joan Levy Ph.D., Chief Science Officer, at [jlevy@curemelanoma.org](mailto:jlevy@curemelanoma.org) before applying. Applications from PIs who do not meet the eligibility criteria will not be reviewed.

**Evaluation Criteria:**

All proposals will be evaluated on:

- Scientific importance of work to identify or validate diagnostic, prognostic, or predictive biomarkers and/or associated technologies that will aid in the detection, diagnosis, treatment, and management of the disease;
- Technically feasible proposals that are appropriate to provide the data needed to secure additional funding for further project development and advancement to clinical application;
- Qualifications of the research team and adequacy of resources and environment;
- Appropriateness of budget tied to a reasonable milestone/timeline plan. (reviewed specifically by MRA staff)

## Application Format:

### Step 1: Letter of Intent Submission:

A one-page letter of intent **must** be uploaded into OneDrive using this link: [Letter of Intent Next Steps Award Melanoma Biomarker Validation](#) no later than **July 31, 2024 by 11:59 PM EST**. This LOI is used for administrative purposes and will not be peer reviewed. **You will receive confirmation via email from MRA that your LOI has been received so please provide your name and contact information following the instructions below.** If MRA identifies any administrative issues, **we will notify you by August 6<sup>th</sup> the latest. If we have not received a LOI by the July 31, 2024 deadline, you will not be eligible to submit a full application.**

### The one-page LOI **MUST** include the following information:

- **PI:** Name, institution, position title, email address and phone number in the upper left-hand corner of the document;
- **Title** of proposal;
- **Brief description** of the goal of the project and specific aims;
- **Nature and rationale** for any proposed collaboration and the specific role of each participant;
- **List names and affiliations** of all key personnel
- No institutional approval required for LOI submission

**Please note: Maximum length of LOI is one page. The preference is to submit file as a pdf to OneDrive.**

### Step 2: Full Application Submission:

**Applications must be submitted by 11:59 PM EST on September 5, 2024.** Proposals **will not** be considered after the deadline. Applicants must utilize the Proposal Central online application tool at <https://ProposalCentral.com/> and the document templates and requirements therein. Please carefully follow the instructions in Proposal Central and below. **PLEASE NOTE: PROPOSAL CENTRAL WILL NOT BE OPEN UNTIL THE WEEK OF JULY 8<sup>TH</sup> BUT YOU CAN VIEW THE FULL APPLICATION INSTRUCTIONS LISTED BELOW.**

### Full application submission includes the following steps and components:

1. **Title Page:** Enter the project title. Please note: the grant title (along with the PI's name and institution) will become public if the award is selected for funding, therefore, it should not contain any proprietary information.
2. **Templates and Instructions:** Download RFP and templates.
3. **Enable Other Users to Access this Proposal:** Allow others (e.g., institutional administrators or collaborators) to view, edit, or submit your proposal. Electronic signatures are required to submit the application. ***The Signing Official from the applicant's institution must be provided at least 'Edit' access on this screen to be able to sign.*** Please review the Signature Page to confirm the signature roles required and add as appropriate on this page.  
**\*PLEASE MAKE SURE TO GRANT ACCESS AHEAD OF TIME TO YOUR INSTITUTION'S SIGNING OFFICIAL TO AVOID ANY LAST-MINUTE ISSUES WITH SIGNING AND SUBMITTING YOUR APPLICATION. \***

4. **Applicant/PI:** Key information about the applicant PI.
5. **Organization/Institution:** Key information about the PI's institution, including name and email address of the signing official who, in addition to the PI, will be contacted if the award is selected for funding. If your institution has a [ROR](#) (Research Organization Registry ID), please include.
6. **Key Personnel:** List and provide contact information for key persons. Include everyone **except the applicant** who will contribute to the scientific development or execution of the project in a substantive, measurable way whether they receive salaries or compensation under the grant. ORCID ID is required only for the PI.

**Descriptions of Key Personnel roles:**

**Principal Investigator (PI):** This is the applicant for this award who will also serve as project leader and primary point of contact for MRA Staff if multiple investigators and collaborators are involved. The PI will ensure that the team complies with the terms of the award, including all reporting, contractual, and financial obligations. Co-PIs are **not** allowed.

**Co-Investigator:** Co-I's are vital scientific contributors (at the same or a different institution from the PI), often bringing a needed expertise to the research team. They commit some level of measurable effort to the project and are, therefore, always designated as Key Personnel whether being compensated or otherwise.

**Collaborator:** Play a lesser role in the thinking and logistics of the project than a Principal Investigator or Co-Investigator. Depending on the role and effort, a collaborator may be designated as Key Personnel (although not required) and may be compensated.

**Consultant:** Provides guidance on specific aspects of the research project, as their expertise applies. A consultant may be designated as Key Personnel (although not required) and may be compensated.

**Others:** Key Personnel may also include (but are not required) people at the master's or baccalaureate level (such as Project Managers, Technicians, Postdoctoral Associates, Fellows, Research Assistants or Graduate Students), if they will contribute to the scientific development or execution of the project in a substantive, measurable way whether they receive salaries or compensation under the grant.

REQUIRED SUPPORTING DOCUMENTS FOR KEY PERSONNEL					
Personnel	Include in KP Section	Biosketch	Current/Pending Support	Letter of Support	ORCID ID required
<b>Principal Investigator</b>	Yes (All)	Yes	Yes	N/A	Yes
<b>Co-Investigator</b>	If applicable	Yes	No	Optional	No
<b>Collaborator</b>	If applicable	Yes, if included as KP	No	Optional	No
<b>Project Manager</b>	Optional	Yes, if included as KP	No	No	No
<b>Technician</b>	Optional	Yes, if included as KP	No	No	No
<b>Consultant</b>	If applicable	Yes, if included as KP	No	No	No
<b>Postdoctoral/Fellow</b>	Optional	Yes, if included as KP	No	No	No
<b>Graduate Student</b>	Optional	Yes, if included as KP	No	No	No
<b>Other (such as research asst, etc)</b>	Optional	Yes, if included as KP	No	No	No

7. **Data and Renewable Reagent Sharing Plan:** In order to promote rapid research advancement, transparency, reproducibility, and collaboration, MRA encourages the open sharing of data and resources generated from its funded awards. Provide information for the types of data and renewable reagents that will be generated as part of the award and how they will be shared.

MRA will incur costs associated with policy compliance, provided these fees (e.g., article processing charges, data storage), are included in the original grant application budget.

8. **Abstracts and Keywords:** Provide a general audience abstract (non-technical) and a technical abstract (2,000 characters, *including spaces*, maximum each) and keywords. Please note: the general audience abstract will become public if the award is selected for funding, therefore, it should not contain any proprietary information.
9. **Budget Period Detail:** Enter budget details for each award period requested. Awards will not support indirect costs, overhead costs, or other similar institutional charges. Fringe benefits for personnel salaries are allowable. Please also include any costs associated with compliance with MRA's data sharing policy. **Furthermore, the budget should align with the milestone/timeline plan proposed in the project description.** Therefore, if applying for a 2-year award, the budget does **not** have to be split evenly over the two years. **Please note: MRA recognizes that research studies will need a certain amount of upfront funding support to initiate the project. Therefore, an initial payment upon full execution of the grant award can be included as the first milestone with an associated budget. Applications that do not have a milestone/timeline plan included in the project description will not be reviewed.**

10. **Budget Summary and Justification:** A summary of the budget details will be shown in this step. In addition, provide sufficient detail for the evaluation of the major portions of the budget that are being requested. If more space is required than is provided in the Proposal Central forms (2,000 characters), applicants may upload the budget justification in document form in step 13.

11. **Current and Pending Research Support:** Please list all current and pending support for the Applicant.

Any overlap of current or pending support with the MRA Next Step proposal must be described and explained. Current and pending support can be added to your (and other Key Personnel's) Professional Profile on Proposal Central by clicking on the 'Professional Profile' tab and going to Step #6: Other Support.

**To add your entries, please click on the "+" link and all entries previously saved in your Professional Profile will show. Please select the applicable support and save.**

12. **Organizational Assurances:** IRB and IACUC approvals, if applicable.

13. **Upload Attachments: Upload the following:**

- a. **Biosketch for PI and Key Personnel:** Please upload an NIH format biosketch for yourself and all Key Personnel listed in step #6. Biosketches for research support staff, students, postdocs, and other training positions are not required. Applicants who do not have an NIH biosketch may use the template provided in Proposal Central. Besides publications, MRA welcomes the inclusion of research outputs such as datasets, code, patents, and papers posted to preprint servers.
- b. **Current and pending research support:** Whenever possible, please enter PI current and pending support directly into Proposal Central in the "Current and Pending Support" section (step #11). Any overlap of current or pending support with the Next Step proposal must be described and explained.
- c. **Project description:** Must be formatted in Arial 11-point or Times New Roman 12-point font with no less than ½ inch margins. The project description should be **5 pages maximum**, inclusive of the following: Any figures to be included can be embedded within this section. Project description should include: **1. Project Background:** Hypothesis and Specific Aims; **2. Pertinent preliminary data;** **3. Experimental Design** including resources available and collaborative efforts; **4. Detailed milestone plan incorporating a timeline** noting that there is a 2-year award limit. Payment schedule in budget should be associated with milestone plan and timeline. This section **must** be included in the project description for application to be reviewed; **5. Rationale/Fit** for this proposal to generate data needed leading to well-developed hypothesis-driven research proposals with enough preliminary data to prepare for future grant submissions.



- d. **Literature references:** A list of up to 30 references supporting the project description is allowed, in addition to the 5-page project description.
  - e. **Application checklist:** Please complete the checklist to ensure that all application materials are provided, and that the applicant is eligible to apply.
14. **PI Data Sheet:** Please enter your ORCID ID and other requested demographic information. If you do not have an ORCID ID, you can register for one here: <https://orcid.org/register>. Please note that requested demographic information will NOT be used by MRA in any way during the selection process. Having such information will help MRA better understand its applicant and awardee pool and detect and address any inequities identified.
15. **Validate:** Check for any missing required information.
16. **Signature Page(s):** *Before submitting the application*, an electronic signature is required from both the Applicant/PI and a Signing Official from the applicant’s institution. Type your name in the text box and click the green ‘Sign’ button. A date and time stamp will appear next to the button indicating that the electronic signature was successful. To give the Signing Official access to sign this application, enter their information in Step #3: “Enable other users to access this proposal” and grant them at least “Edit” access.
17. **Submit:** Please note that no proposals will be able to be submitted past their deadline. Technical support for the on-line application system is not available after 11:59 p.m. Eastern Time or on weekends.

**PLEASE MAKE SURE TO ALLOW ENOUGH ACCESS AHEAD OF TIME TO YOUR INSTITUTION’S SIGNING OFFICIAL TO AVOID ANY LAST-MINUTE ISSUES WITH SIGNING AND SUBMITTING YOUR FULL APPLICATION BY SEPTEMBER 5, 2024!**