

2020-2021 REQUEST FOR PROPOSALS

SECOND RELEASE

August 31, 2020

The Melanoma Research Alliance (MRA) is pleased to announce its second release of the Request for Proposals (RFP) for the 2020-2021 cycle. This second release adds a new Established Investigator Award Special Opportunity focused on melanoma brain metastasis jointly funded by The Rising Tide Foundation for Clinical Cancer Research (RTFCCR) and MRA. MRA and RTFCCR will partner to fund up to two awards with this focus.

MRA's Initial RFP released for this cycle was announced on August 3, 2020. For your convenience, **the First Released RFP (starting with a table of contents) is appended to this Second Release starting on page 3**. **Information on eligibility, key criteria, and instructions on how to apply for any and all awards this cycle are included in this appended document as noted in the Table of Contents on page 3**.

An investigator may serve as PI on only one proposal submitted to MRA for any of the mechanisms in this cycle, including any and all Special Opportunity Awards. The deadlines for all applications remain unchanged since the first release of the RFP. MRA plans to award at least \$7.6 million for all awards announced during the 2020-2021 cycle.

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Rachel Fischer, Ph.D., at <u>rfischer@curemelanoma.org</u>.

SPECIAL OPPORTUNITY ESTABLISHED INVESTIGATOR AWARD: RTFCCR-MRA Established Investigator Awards on Melanoma Brain Metastasis

Proposals due 5 p.m. Eastern Time, November 4, 2020

Although recent advances in treating late stage melanoma have improved patient outcomes, many patients do not respond at all or eventually see their disease progress. Up to 50% of these patients will develop clinically detectable brain metastases, with up to 70% of patients having brain metastases at autopsy. Brain metastases are often the initial site of treatment failure, and for patients whose brain metastases do respond to treatment, the responses are often of shorter duration compared to metastases in other organs. For these reasons, a better understanding of how melanoma spreads to the brain, identification of new therapeutic targets and biomarkers to predict brain metastases, and understanding of how best to combine and/or sequence available therapies, among other questions, are essential to advance progress in treating melanoma brain metastases.

To address this critical unmet need, the Rising Tide Foundation for Clinical Cancer Research (RTFCCR) and MRA will partner to fund two Established Investigator Awards focusing on <u>clinical studies</u> that address prevention, and treatment of melanoma that metastasizes to the brain. Applications should propose projects ready to move to the next stage of research (e.g. from preclinical/translational to Phase I clinical trial; from Phase I to Ib/II clinical trial; from biomarker discovery to validation in larger cohorts). Proposals can include but are not limited to the following:

- Characterizing how brain metastases change in response to treatment and/or become resistant to treatment to inform approaches to prevent or overcome resistance in patients;
- Understanding how best to combine and/or sequence therapeutic approaches, including but not limited to systemic therapies and/or stereotactic radiotherapy, to effectively treat brain metastases;
- Validating biomarkers or other technologies to monitor for and/or predict brain metastasis in patients so as to better inform/guide clinical treatment options.

Please see descriptions of and instructions for Established Investigator Awards for specific details on eligibility, award terms and amount, as well as instructions on how to apply. Applicants should submit to the general Established Investigator Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please select "Brain Mets" under subprogram in the Title Page step of the online application. Selecting "Brain Mets" will not limit an applicant's opportunity to also be selected under the general Established Investigator Award, but instead is meant to expand opportunities in an effort to increase overall funding of approaches for melanoma brain metastases to improve patient outcomes.

If selected for funding, awardee will be asked to prepare separate budgets with 50% of support coming from RTFCCR and MRA. Each funder's financial support will be governed by its own award agreement terms and conditions with the Administrative PI's institution.

2020-2021 REQUEST FOR PROPOSALS

August 3, 2020

The Melanoma Research Alliance (MRA) is pleased to announce a Request for Proposals (RFP) for preclinical, translational, and early clinical research with the potential to produce unusually high impact, nearterm advancements in melanoma prevention, detection, diagnosis, staging, and treatment. This cycle, proposals will be accepted for Established Investigator Awards, Academic-Industry Partnership Awards (for Established Investigators), Young Investigator Awards, Pilot Awards, and Special Opportunity Awards in Immunotherapy, Radiation Oncology, and Pediatric Melanoma. MRA plans to support at least \$7.6 million in new funding in the 2020-2021 cycle.

TABLE OF CONTENTS

Introduction	page 2
Objective	page 2
Review and Selection Criteria	page 3
Applicant Eligibility	page 3
Types of Awards	page 4
Application Format and Instructions	page 9
Timeline	page 12
Review Mechanism	page 13
Collaborative Funding Offers	page 13
Award Administration	page 13
Frequently Asked Questions	page 14
Additional Information and Contacts	page 18

INTRODUCTION

About Melanoma: According to the National Cancer Institute, melanoma is the sixth most common cancer in the United States and rates continue to increase among older age groups. More effective options for patients and those at risk are urgently needed. While research and treatment have advanced significantly in recent years, leading to the availability of immunotherapies and molecularly targeted therapies for patients, there remains a substantial need for developing new treatment approaches, including treatment approaches for rare melanoma subtypes, optimizing the effectiveness of existing and emerging therapies, and better preventing, detecting, and diagnosing melanoma. From a basic and clinical research perspective, melanoma occupies the crossroads of molecular biology and immunology. Cutaneous melanomas can be analyzed at the earliest stages of carcinogenesis for molecular events or signatures predicting progression, invasion, and dissemination. As one of the most immunogenic human tumors, melanoma also provides an ideal context for understanding interactions between the human immune system and cancer. Recent therapeutic progress offers unprecedented means to explore melanoma in ways never before possible.

About the MRA: MRA is a public charity formed in 2007 under the auspices of the Milken Institute, with the generous founding support of Debra and Leon Black. The mission of MRA is to **end suffering and death due to melanoma** by collaborating with all stakeholders to accelerate powerful research, advance cures for all patients, and prevent more melanomas. To date, the MRA has awarded \$123 million to support 339 research projects in 18 countries. Please visit <u>www.curemelanoma.org</u> for further information on MRA and the research initiatives funded in prior award cycles.

OBJECTIVE: EMPHASIS ON TRANSLATIONAL SCIENCE

MRA is soliciting proposals that address the gap in translational science (i.e., turning scientific discoveries into tools and/or treatments for high-risk individuals and patients with melanoma). Successful proposals have the potential of applying important basic and preclinical discoveries to the near-term development of clinical trials and studies impacting melanoma detection, prevention, diagnosis, staging, and/or treatment.

Proposals for clinical studies testing well-defined and clearly articulated hypotheses are welcome and should be accompanied by a brief protocol synopsis and timeline with milestones. IRB approval is not required at the time of application but is required before initial payments are made. **MRA welcomes proposals in the following areas:**

- **Prevention:** Elucidation of environmental, epidemiological, and biological factors in melanomagenesis that lead to improved strategies for melanoma prevention.
- **Detection, Diagnosis, and Staging:** Development of innovative detection and diagnostic methodologies; identification and validation of diagnostic and prognostic biomarkers.
- **Treatment:** Projects emphasizing the translation of scientific findings to new treatments for patients with melanoma. Examples include, but are not limited to, studies of melanoma immunotherapy, therapeutic applications based on molecular mechanisms involved in melanoma formation and/or progression, treatments that target the tumor microenvironment or microbiome, combination therapies, and development of novel biomarkers of response to therapy.

Special Emphasis Areas: For the 2020-2021 cycle, MRA seeks proposals in the following areas, which are focused on current unmet clinical needs in melanoma. These areas are of particular interest, will receive special consideration, and can include pre-clinical, translational, clinical, and/or correlative studies:

- Identifying strategies to overcome primary and secondary treatment resistance;
- Developing treatment strategies for difficult-to-treat melanoma subtypes such as acral, mucosal, or uveal melanoma, and/or non-BRAF mutant melanomas including NRAS and NF1 mutants;
- Uncovering novel mechanisms of melanoma initiation and progression in order to improve prevention and early detection strategies, develop early treatment approaches such as adjuvant and neoadjuvant therapies, and identify prognostic biomarkers of high-risk disease/precursor lesions; and
- Developing strategies to prevent and/or treat metastatic disease, including in transit and/or satellite metastases, and leptomeningeal disease.

REVIEW AND SELECTION CRITERIA

The following criteria will be used to assess the importance, originality, rigor, translational nature of, and degree to which the proposal will lead to rapid clinical benefit.

- **Overall Scientific and Clinical Importance:** Original, innovative, and transformative research approaches with strong scientific rationale and clear capacity to enhance prevention, detection, diagnosis, staging, and/or treatment for patients with melanoma or for individuals at risk will be prioritized. Proposals that articulate a clear path to near-term clinical application will be strongly favored.
- **Rigor and Feasibility:** MRA seeks outstanding and technically rigorous proposals as determined by peer review. Overall study design, methodology, and analyses must be feasible and appropriate to accomplish specific aims.
- Investigator/Environment: Applicant has appropriate training, expertise, and evidence of productivity (inclusive of publications, datasets, code, patents, etc), to carry out proposed research. Applicant's institution and department are sufficiently committed to area of research proposed and to the applicant. Equipment and other institutional resources are sufficient to support the applicant. In the case of Young Investigator applicants, selected Mentor is appropriate to advance applicant's career and project with evidence of a strong mentorship relationship.
- For Established Investigator, Academic-Industry Partnership, and Pilot applications, each of the above criteria will account for approximately one-third of the overall score.
- Young Investigator applications will be evaluated using the above criteria; however, will be approximately weighted as follows: One-third Scientific and Clinical Importance, Rigor and Feasibility, one-third Investigator, and one-third Environment/Mentor.

APPLICANT ELIGIBILITY

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 at an academic or other non-profit research institution within or outside the United States. Please note, however, that the ASTRO-MRA Young Investigator Award is limited to U.S. applicants only, and the Rosetrees Trust-MRA Young Investigator is limited to UK and Israel-based applicants only.
- PIs must be able to show clear evidence of an independent research program.
- If previously funded by MRA, applicant must be up-to-date on all reporting requirements.
- Fellows or those in other training or research support positions are not eligible to apply.
- Individuals employed by state or federal government agencies may participate in research proposals as non-funded collaborators, but may not apply for MRA funding.
- Investigators need not be specifically trained in melanoma research; however, they should be working in an environment capable of conducting high-quality, high-impact melanoma research.
- <u>An investigator may serve as PI on only one proposal submitted to MRA for any of the award</u> mechanisms in this cycle. This includes any Special Opportunity Awards.
- Mentors for Young Investigator Award applicants may serve as a PI on a separate proposal this cycle; however, that proposal must represent a distinct hypothesis from the Young Investigator's proposal.
- Multiple applications will be accepted from a single institution, provided that each application has a different PI and represents a distinct hypothesis.

If there are any questions about eligibility, please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at <u>rfischer@curemelanoma.org</u> before submitting an application. Applications from PIs who do not meet the eligibility criteria will not be reviewed.

TYPES OF AWARDS

YOUNG INVESTIGATOR AWARD

Applicant Eligibility Checklist due October 21, 2020 Full proposals due 5 p.m. Eastern Time, November 4, 2020

Description: Young Investigator Awards aim to attract early career faculty with original ideas into the field of melanoma, thereby recruiting and supporting the next generation of melanoma research leaders. Awardees will be provided funding to accomplish innovative and original, preclinical, translational, and/or early clinical research projects. Young Investigators are scientists within the first four years of their first academic faculty appointment. A mentorship commitment from a senior investigator is required.

Term: 3 Years

Amount: Up to \$75,000 per year for three years (up to \$225,000 total)

Eligibility Requirements:

- Applicants must be within the first four years of their first independent, full time academic faculty appointment at the application deadline, at the level of Assistant Professor (or equivalent position);
- Applicants must designate at least one Mentor who is an established investigator at the same institution who will ensure that adequate support and guidance are provided for successful completion of the proposed research project and provide career mentorship;
- Applicants who have secured an independent full-time faculty position commencing by June 1, 2021 will be considered; in this case, a letter from an institutional official or department chairperson confirming the planned date of faculty appointment is required at the time of application;
- Applicants do not have to be on a tenure-track; however, fellows or others who are in training positions are not eligible to apply;
- Applicants who are in research support positions are not eligible to apply;
- Applicants who have been awarded a prior MRA Young Investigator Award are not eligible to apply for an additional MRA Young Investigator Award;
- Applicants may serve as PI on only one proposal submitted to MRA for any of the award mechanisms in this cycle;
- All Young Investigator applicants must complete and return the Applicant Eligibility Checklist by October 21, 2020. Please email the completed checklist to Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration at <u>rfischer@curemelanoma.org</u>.

ESTABLISHED INVESTIGATOR AWARD

Full proposals due 5 p.m. Eastern Time, November 4, 2020

Description: Established Investigator Awards support senior investigators with an established record of scientific productivity and accomplishment.

Term: 3 Years

Amount: Up to \$125,000 per year for three years (up to \$375,000 total)

Eligibility:

- Applicants must be a senior investigator, past the initial four years of their first academic faculty appointment.
- Applicants must hold a full-time faculty appointment at the level of Assistant Professor (or equivalent) or above.

ESTABLISHED INVESTIGATOR ACADEMIC-INDUSTRY PARTNERSHIP AWARD

Full proposals due 5 p.m. Eastern Time, November 4, 2020.

Description: The Academic-Industry Partnership Award (for Established Investigators) is designed to enhance translational research by extending academic capabilities to clinical investigations and to

facilitate interactions between the academic and industrial research sectors. These awards will be cofunded by MRA and an industry partner whose involvement is essential to the project.

Term: 3 years

Amount: Up to \$125,000 per year for three years (up to \$375,000 total). Industry partner must provide funds and/or in-kind support (e.g., reagents, clinical grade drugs, equipment, and contract services) that matches or exceeds MRA funds for the award period. Non-contract industry personnel costs may not be counted as in-kind support.

Eligibility:

- Applicants must be a senior investigator, past the initial four years of their first academic faculty appointment.
- Applicants must hold a full-time faculty appointment at the level of Assistant Professor (or equivalent) or above.
- Applicants must identify an industry partner at the time of application.
- Industry scientists may serve as co-investigators or collaborators, but may not be PIs.

Additional Information:

Industry will negotiate contract terms directly with the PI's institution and will dispense its portion of the research funds directly to that institution. In the event that an award is granted by MRA, **both a finalized contract between the industry partner and the institution, as well as a letter agreement between the industry partner and MRA, must be executed within 90 days of the award date.** Funds will not be dispensed until such a contract and agreement are in place and, MRA may withdraw its offer of award if such a contract and agreement are not in place within the 90-day period.

PILOT AWARD

Full proposals due 5 p.m. Eastern Time, November 4, 2020

Description: Pilot Awards support senior investigators who propose potentially transformative ideas that do not have extensive preliminary data but articulate a clear hypothesis and translational goals. Resources for such "high-risk, high-reward" projects are important to establish proof-of-concept, which may then leverage additional funding through more traditional avenues.

Term: 2 Years

Amount: Up to \$50,000 per year for two years (up to \$100,000 total)

Eligibility:

- Applicants must be a senior investigator, past the initial four years of their first academic faculty appointment;
- Applicants must hold a full-time faculty appointment at the level of Assistant Professor (or equivalent) or above.

SPECIAL OPPORTUNITY: BRISTOL MYERS SQUIBB-MRA YOUNG INVESTIGATOR AWARDS IN IMMUNOTHERAPY

Applicant Eligibility Checklist due October 21, 2020 Full proposals due 5 p.m. Eastern Time, November 4, 2020

Through the generous support of Bristol Myers Squibb (BMS), MRA is offering three awards for Young Investigators to conduct projects supported by preliminary data and focused on advancing immunotherapies in melanoma.

Please see descriptions of and instructions for Young Investigator Awards for specific details on eligibility, award terms, and amount, as well as instructions on how to apply.

Applicants should submit to the general Young Investigator Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please select "BMS Immunotherapy" under subprogram in the Title Page step of the online application. Selecting "BMS Immunotherapy" will not limit an applicant's opportunity to also be selected under the general Young Investigator Award, but instead is meant to expand opportunities in an effort to increase overall funding of immunotherapy approaches for melanoma.

SPECIAL OPPORTUNITY: ASTRO-MRA YOUNG INVESTIGATOR AWARD IN RADIATION ONCOLOGY

Applicant Eligibility Checklist due October 21, 2020 Full proposals due 5 p.m. Eastern Time, November 4, 2020

Research in radiation oncology has led to advancements in technology and therapy that have improved patient outcomes and care. The MRA is pleased to partner with the <u>American Society for Radiation</u> <u>Oncology (ASTRO)</u> to offer a special opportunity to support research in radiation oncology to improve treatment options for melanoma patients. Early career radiation oncologists, radiation or cancer biologists, or physicists are encouraged to submit radiation oncology Research Proposals that include at least 50% effort on melanoma.

Please see descriptions of and instructions for Young Investigator Awards for specific details on eligibility, award terms and amount, as well as instructions on how to apply. Additional eligibility criteria include:

- <u>Applicant must hold a position at an academic or other non-profit research institution within the</u> <u>United States; and</u>
- Applicant must be a member in good standing of ASTRO at time of award activation (June 1, 2021 unless otherwise noted).

Applicants should submit to the general Young Investigator Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please select "ASTRO-MRA" under subprogram in the Title Page step of the online application. **Selecting** "ASTRO Radiation Oncology" will not limit an applicant's opportunity to also be selected under the general Young Investigator Award, but instead is meant to expand opportunities in an effort to increase overall funding of radiation oncology approaches for melanoma.

Please see instructions below on how to apply. Please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration at rfischer@curemelanoma.org with any questions.

SPECIAL OPPORTUNITY: ST. BALDRICK'S FOUNDATION-MRA YOUNG INVESTIGATOR AWARD IN PEDIATRIC MELANOMA

Applicant Eligibility Checklist due October 21, 2020 Full proposals due 5 p.m. Eastern Time, November 4, 2020

Although multi-institutional studies and patient registries have improved our understanding of pediatric melanoma in recent years, a complete understanding of this disease, as well as how best to diagnose and treat pediatric melanoma patients remains a critical unmet need. The MRA is pleased to partner with <u>St. Baldrick's Foundation</u> to offer a special opportunity to support research to improve the diagnosis, understanding, and treatment of pediatric melanoma. Early career faculty are encouraged to submit research proposals addressing the following Special Emphasis Areas:

- Identifying novel techniques and biomarkers to aid in accurate diagnosis and optimize management of pediatric/adolescent patients;
- Elucidating the underlying mechanisms of melanoma development in pediatrics;
- Understanding clinical differences in presentation between pediatric and adult melanoma;
- Collecting real-world data on pediatric melanoma to inform the biological basis for melanoma formation in children versus adults; and
- Analyzing similarities and differences between melanoma in children/adolescents and in adults relevant to immunogenicity and potential impact of immunotherapies.

Please see descriptions of and instructions for Young Investigator Awards for specific details on eligibility, award terms and amount, as well as instructions on how to apply.

Applicants should submit to the general Young Investigator Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please select "St. Baldrick's Pediatric Melanoma" under subprogram in the Title Page step of the online application. Selecting "St. Baldrick's Pediatric Melanoma" will not limit an applicant's opportunity to also be selected under the general Young Investigator Award, but instead is meant to expand opportunities in an effort to increase overall funding of research to improve the diagnosis, understanding, and treatment of pediatric melanoma.

Please see instructions below on how to apply. Please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration at <u>rfischer@curemelanoma.org</u> with any questions.

SPECIAL OPPORTUNITY: ROSETREES TRUST-MRA UK- OR ISRAEL-BASED YOUNG INVESTIGATOR AWARD

Applicant Eligibility Checklist due October 21, 2020 Full proposals due 5 p.m. Eastern Time, November 4, 2020 The MRA is pleased to partner with the <u>Rosetrees Trust</u> to offer a special opportunity to fund a Young Investigator Award focused on melanoma research from United Kingdom- and Israel-based researchers.

Please see descriptions of and instructions for Young Investigator Awards for specific details on eligibility, award terms and amount, as well as instructions on how to apply. Additional eligibility criteria include:

• Applicants must be based at an institution located in the United Kingdom or Israel.

Applicants should submit to the general Young Investigator Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please select "Rosetrees Trust" under subprogram in the Title Page step of the online application. Selecting "Rosetrees Trust" will not limit an applicant's opportunity to also be selected under the general Young Investigator Award, but instead is meant to expand opportunities in an effort to increase overall funding of early career investigators focused on melanoma who are based in the UK or Israel.

Please see instructions below on how to apply. Please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration at <u>rfischer@curemelanoma.org</u> with any questions.

APPLICATION FORMAT AND INSTRUCTIONS (ALL AWARDS)

All applications are due by 5:00 p.m. Eastern Time. Proposals will not be considered after the deadline. Applicants must utilize the proposalCENTRAL online application tool at <u>https://proposalcentral.com/</u> and the document templates and requirements therein. Please carefully follow the instructions in proposalCENTRAL and below. Applications include the following steps and components:

- 1. Title Page: Enter the project title.
 - For Young Investigator proposals: Under subprogram, select Special Opportunity if applicable (otherwise select N/A).
 - For Academic-industry Partnership proposals: Include name of Industry Partner.
- 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.
- 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.
- 6. **Key Personnel:** List and provide contact information for key persons. For Young Investigator Award applicants, a Mentor from the same institution is required.

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 has adopted the following Data Sharing Policy:

- MRA **recommends** the posting of manuscripts based on or developed under an MRA Award to a pre-print server ahead of or at the time of journal submission.
- MRA **recommends** the posting of research outputs (data, code, software) to public data repositories at the time such research outputs are generated.
- MRA **recommends** that manuscripts based on or developed under an MRA Award be published in open-access journals.
- MRA recommends that all research outputs based on or developed under an MRA Award (including publications, data, code, and software) be made available with no commercial modification rights (e.g. <u>CC BY-NC license</u>).
- MRA **requires** that the final, accepted version of any publication based on or developed under an MRA Award be deposited in PubMed Central so that it is available 12 months after publication.
- MRA **requires** that any data, code, and/or software needed for the independent verification of published research results based on or developed under an MRA Award be curated and made freely and publicly available at the time of publication.

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 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 detail 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 to MRA's data sharing policy. For Academic-Industry Partnership applications, the budget should contain all costs associated with the project including contributions from both MRA and the industry partner, and the expected contributions from each should be clearly explained in the Budget Justification.
- 10. **Budget Summary and Justification:** A summary of the budget detail 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 proposalCENTRAL forms (2,000 characters), applicants may upload the budget justification in document form in step #13. For Academic-Industry Partnership applications, the budget should contain all costs associated with the project including contributions from both MRA and the industry partner, and the expected contributions from each should be clearly explained in the Budget Justification.

- 11. **Current and Pending Research Support:** Please list all current and pending support for the Applicant and all Key Personnel. <u>Any overlap of current or pending support with the MRA proposal must be described and explained.</u> If you cannot access the proposalCENTRAL profiles of Key Personnel, please use the template provided in step #2 to upload this information in step #13.
- 12. **Organizational Assurances:** IRB and IACUC approvals, if applicable. Please note that that use of human embryonic stem cells is not permitted for applications that wish to be considered for the St. Baldrick's Foundation MRA Young Investigator Award in Pediatric Melanoma.

13. Upload Attachments: Upload the following:

- a. **Biosketch for PI and Key Personnel**: Please upload an NIH format biosketch for yourself and any Key Personnel. 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 proposalCENTRAL. Besides publications, MRA welcomes the inclusion of research outputs such as datasets, code, patents, and papers posted to preprint servers.
- a. **Current and pending research support:** Use the template provided in proposalCENTRAL, which includes a statement of overlap, for any Key Personnel not included in step #11. <u>Any overlap of current or pending support with the MRA proposal must be described and explained.</u>
- b. **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: Background and specific aims, preliminary data, experimental design and methods, statistical plan, figures (which may be embedded within the above sections), and rationale/fit with key criteria, including the potential for clinical impact.
- c. Literature references: A list of up to 20 references supporting the project description is allowed, in addition to the 5-page project description.

d. For Young Investigator Award proposals:

- i. Mentor Letter of Support: Include a letter of support from an established scientific Mentor at the same institution, who is familiar with the applicant and his/her work and will provide guidance and support for the project. The Mentor's letter should confirm that the applicant has an independent research program and include a brief statement about the applicant, the Mentor's role, mentoring plan, the research environment, and sources of institutional support that the applicant will utilize in conducting the project. MRA recognizes that unconscious bias can manifest in such support letters and therefore strongly recommends considering these or similar guidelines when preparing such letters: <u>https://tinyurl.com/yapwnw3a</u>
- ii. Young Investigator Applicant Eligibility Checklist: Required to confirm eligibility. Requires signature of the Department Chair, Division Head, or Dean. Must be returned via email to Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at <u>rfischer@curemelanoma.org</u> by October 21, 2020. Please also upload a copy as part of the application.
- e. **For Academic-Industry Partnership Award proposals:** Include a letter of support from the industry partner, which should include at a minimum:

- i. A description of the total amount of support, clearly indicating the portion that is monetary and/or in-kind, for the full term of the award (which must match the total funding requested in this application).
- ii. Acknowledgement that if the Award is made the industry partner will execute an agreement with the awardee Institution within 90 days.
- iii. Acknowledgement that if the Award is made the industry partner will execute an agreement with MRA within 90 days. An example template agreement may be requested from MRA. Any questions about this can be directed to Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration at rfischer@curemelanoma.org.
- f. **For proposals involving clinical trials:** Attach a brief protocol synopsis (5 pages maximum), along with a timeline and milestones, including but not limited to IRB and regulatory approval (if applicable), patient accrual timeline, and timeline for completion of analyses.
- g. **Application checklist:** Please fill out to ensure all application materials are complete and applicant is eligible to apply.
- 14. **Statement of Proposal's Fit Within MRA's Research Program**: Provide a brief statement (up to 2000 characters) of how the proposed research project fits within MRA's overall research portfolio, which can be found here: <u>https://www.curemelanoma.org/grants/</u>. If the work builds on a previously funded project(s), please explain.
- 15. **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.
- 16. Validate: Check for any missing required information.
- 17. **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.
- 18. **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 5:00 p.m. Eastern Time or on weekends.

TIMELINE

All application deadlines conclude at 5:00 p.m. Eastern Time. Proposals submitted after the deadline will not be considered.

- October 21, 2020: Deadline for Young Investigator applicants to submit Applicant Eligibility Checklist.
- November 4, 2020: Applications are due for all award mechanisms.

- **Early April 2021:** Awardees notified (Note that MRA may adjust the notification date without notice to applicants).
- June 1, 2021: Projects start.

REVIEW MECHANISM

All proposals will undergo rigorous peer review by the MRA Grant Review Committee (GRC), comprised of experts in diverse areas of translational cancer research (Full listing of the MRA GRC is available here: www.curemelanoma.org/GRC). Applications will be scored according to MRA Review and Selection Criteria. To minimize any real or perceived conflicts of interest (COI), MRA asks GRC members to adhere to a rigorous set of COI guidelines. Further information about these guidelines are available upon request. Please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at <u>rfischer@curemelanoma.org</u>. All awards are contingent upon ratification by the MRA Board of Directors. MRA will make every effort to provide brief, written reviewer feedback on full applications to all applicants; however, occasionally such comments may not be available due to unforeseen circumstances. A listing of all research projects funded by MRA, along with abstracts, are provided on our website, and are searchable by investigator, institution, or award at <u>www.CureMelanoma.org/grants</u>.

COLLABORATIVE FUNDING OFFERS

For outstanding research proposals as determined by peer review that are deemed fundable, but <u>that fall</u> <u>beyond MRA's full-funding pay-line</u>, MRA may seek co-funding from applicant institutions in order to support these proposals. MRA will reserve up to \$600,000 of its support for the Collaborative Funding program this cycle. For our Collaborative Funding program, MRA will provide one half of the award funds made under this program and each PI's institution will provide the remaining one half of the relevant budget for that institution. In case of questions, please contact Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at <u>rfischer@curemelanoma.org</u>.

For proposals that meet the above criteria, MRA will contact the institutions for this Collaborative Funding offer, and institutions will be asked to verbally decline or accept the offer within 14 days. Signed agreements between MRA and the institution will be required within 30 days. Collaborative Funding terms are non-negotiable and relevant awardees are automatically considered for this program.

AWARD ADMINISTRATION

AWARD LETTER

Upon acceptance of the award, the PI and his/her employing Institution will be required to sign an Award Letter indicating acceptance of the MRA's Award Terms and Conditions within 30 days, which can be found here <u>https://www.curemelanoma.org/assets/Uploads/TermsandConditions2021.pdf</u>. MRA must be notified in advance and approve any significant changes in research objectives, key personnel (including transfer to another employee), or budget.

APPROVALS

MRA requires certification through proposalCENTRAL of compliance with Human Subjects and Animal Care Assurance as applicable. In cases where ethical/regulatory approval is required to perform the work, such approvals will be required before initial payments are made. This includes local IRB approvals of clinical trials supported by MRA funding. For clinical trials, a timeline and milestones must be included in the application package. Failure to meet these milestones within a reasonable time frame may result in termination of the award.

MULTI-INSTITUTIONAL PROJECTS

For projects including key personnel at other institutions, the PI must verify in advance that funds can be transferred from their institution to the collaborating institution. This requirement can be easily met by attaching a letter from the PI's sponsored programs office stating a commitment to comply with this requirement. Sub-award agreements between collaborating institutions must be executed within 60 days of MRA's execution of the award agreement with the applicant institution.

FUNDING

For all proposals, the level and duration of funding may be adjusted by MRA as appropriate for the scope of the proposal and the funds available. Partial funding will also be considered to obtain proof-of-principle data in support of innovative ideas with transformative potential. <u>Awards will not support indirect costs</u>, <u>overhead costs</u>, or other similar institutional charges; however, fringe benefits for personnel salaries are allowable. Full-term funding will be contingent upon review of annual progress reports and other oversight activities conducted by MRA. Multi-year support is not automatic for any MRA award and is conditioned on submission of complete and accurate progress reports, financial reports, and demonstrated progress on the funded proposal.

MRA SCIENTIFIC RETREAT

PIs will be invited to attend the annual MRA Scientific Retreat. PIs are expected to attend and may be asked to present research findings made under their awards at these meetings. MRA will cover reasonable travel costs related to participation in the Scientific Retreat out of the agency budget, and as such, travel for the retreat should not be included within your submitted budget. Although the 2021 Retreat will be virtual, MRA anticipates resuming in-person Scientific Retreats in 2022.

FREQUENTLY ASKED QUESTIONS

Eligibility

- Q: Must PIs have an academic faculty appointment? Is this a hard-and-fast rule?
- A: PIs must have a full-time appointment at an academic or non-profit research institution at the level of 'Assistant Professor' (or equivalent) or above; however, a tenure-track appointment is not required. Evidence of independent investigator status and an environment conducive and supportive of melanoma research is required. If there is any doubt or question about a PI's eligibility, please contact MRA (contacts provided in this RFP) before an application is submitted. Applications from PIs who do not fit the eligibility criteria will not be reviewed. **To confirm eligibility, Young Investigator applicants must complete the Applicant Eligibility Checklist** (see additional FAQs for Young Investigator applicants).

- Q: Does MRA fund investigators and institutions outside of the United States?
- A: Yes. Investigators at non-profit institutions outside of the United States are eligible. PIs must be at the level of 'Assistant Professor' or equivalent. Academic appointments at institutions outside of the U.S. can differ from those traditionally found in the U.S. Contact MRA if there are any questions about eligibility prior to submitting a proposal. <u>Please note that the ASTRO-MRA Special</u> <u>Opportunity is limited to U.S. applicants only, and the Rosetrees Trust-MRA Special Opportunity is limited to UK- and Israel-based applicants only.</u>

Young Investigator Awards

- Q: I do not hold the title of Assistant Professor but I do hold the title of my institution's entry level, full-time faculty position. Am I eligible to apply?
- A: Appointments such as research assistant professor, adjunct assistant professor, assistant professor research track, instructor, or lecturer may be eligible to apply as long as your institution considers this an independent, faculty-level position and you have independent lab space. Please verify your eligibility by October 21, 2020, by emailing the signed and completed Young Investigator Eligibility Checklist to Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at rfischer@curemelanoma.org.
- Q: I am within my first four years of an Assistant Professor position, but previously held an entry level full-time faculty position such as research assistant professor, adjunct assistant professor, assistant professor research track, instructor, or lecturer, either at my current institution or at a different institution. Am I still eligible to apply?
- A: If you held any independent faculty-level position prior to **November 4, 2016**, then you are not eligible to apply.
- Q: I will be past the first four years of my first faculty appointment at the time the project starts. May I apply for a Young Investigator Award?
- A: Yes, as long as you are within the first four yours of your first faculty appointment <u>at the time of</u> <u>proposal submission</u>.
- Q: I will be past the first four years of my first faculty appointment at the time of application but I took time off for personal, family or professional reasons. Does this count against eligibility?
- A: If an applicant took leave of absence for family or medical leave or other personal or professional reasons, please inquire to MRA about eligibility. An appropriately documented leave of absence will not be counted in the four years of eligibility. Leaves of absence may include: military service (that does not include research training/experience), family leave, and maternity leave. MRA will extend the period of eligibility for a period equivalent to the time away from research.
- Q: I am a Fellow at an academic institution. Am I eligible to apply for the Young Investigator Award?
 A: Generally, no, unless the Fellow title is at least equivalent to Assistant Professor position (which is sometimes the case outside of the U.S.). Those in training positions are not eligible. Only those with a faculty level appointment will be considered. Young Investigator Award applicants who do not hold an 'Assistant Professor' title must contact MRA to verify their eligibility prior to

submitting a proposal (see contact information in this RFP) and complete the Applicant Eligibility Checklist.

- Q: What is the role of the Mentor?
- A: It is expected that Young Investigators are independent faculty members and not in training or in research support positions. However, a Mentor is required to help ensure that the Young Investigator has the resources they need to successfully carry out the work at their institution.
- Q: I would like to have a Mentor that is not at my institution. Is this allowed?
- A: No. All Young Investigator applicants must have a designated Mentor at their institution to help to ensure that the Young Investigator has the resources they need to successfully carry out the work at their institution. An applicant may have additional mentors outside of their institution for other purposes, including providing scientific guidance for the project, but they will not be considered a Mentor for the award.
- Q: Are Mentors of Young Investigator applicants allowed to be a PI of an existing MRA award or award application this cycle?
- A: Yes, however, each research proposal must have a distinct hypothesis and scientific aims.
- Q: Is there a minimum level of effort for the Mentor?
- A: No. Mentors should not be listed as having any percent effort on the award.
- Q: What is the expected level of percent effort for a Young Investigator?
- A: There is no specific requirement around percent effort, but MRA encourages a minimum of 10% effort on the project.
- Q: I hold an appointment at an institution outside of the United States. Am I still eligible to apply for ASTRO-MRA Young Investigator Award?
- A: No. Applicants must hold an appointment at an institution in the U.S.
- Q: I am not a member of ASTRO. Am I still eligible to apply for ASTRO-MRA Young Investigator Award?
- A: Yes, but you must be a member of ASTRO in good standing at the time of award activation. You can join ASTRO by visiting <u>www.astro.org</u>.
- Q: I have previously been awarded an ASTRO Junior Faculty or Career Development Award. Am I still eligible to apply for ASTRO-MRA Young Investigator Award?
- A: No. Previous ASTRO Junior Faculty or Career Development Awardees are not eligible to apply.

Academic-Industry Partnership Awards

- Q: How are partnerships between academic scientists and industry formed?
- A: It is the responsibility of the academic scientist to find an industry partner whose involvement and collaboration will be vital to conducting the research project, or vice versa. However, applicants interested in this mechanism are welcome to seek MRA's guidance on potential industry partners.
- Q: In the application budget, do I itemize expenses associated with only the request from MRA or the total budget from both MRA and industry?

A: The overall budget should contain all costs associated with the project including contributions from both MRA and the industry partner, and the expected contributions from each should be clearly explained in the Budget Justification. The value of in-kind support from industry should be estimated in U.S. Dollars. The amount of funding solely requested from MRA should also be clearly indicated in the Budget Justification.

Collaborative Funding Program

- Q: Is my institution's willingness to participate in the Collaborative Funding Program going to affect my score in this or any future funding cycle?
- A: No. The evaluation by MRA's Grant Review Committee will not be influenced by any co-funding or collaborative funding considerations. Only those proposals that are deemed outstanding by peer review but fall below MRA's pay line for full funding will be considered for MRA's Collaborative Funding Program. The collaborative funding process will be conducted after the scientific review process has been completed.

Application components

- Q: Do I need to have an ORCID ID?
- A: Yes. MRA now requires that all applicants provide an ORCID ID. If you do not have an ORCID ID, you can register for one here: <u>https://orcid.org/register</u>. More information about ORCID IDs can be found here: <u>https://orcid.org/</u>.
- Q: Why is MRA collecting demographic information?
- A: MRA requests that applicants provide demographic information in proposalCENTRAL; however, this information is NOT required and will NOT be used 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 that exist in the selection process.
- Q: How are proposals submitted? Do I need to send a hard copy?
- A: All proposals must be submitted electronically via proposalCENTRAL, <u>https://proposalcentral.com/</u>. ProposalCENTRAL will accept electronic signatures on applications.
- Q: Does MRA require the NIH salary cap to be used when calculating salary and fringe benefit requests for the budget?
- A: No, but applicants may use it at their discretion.
- Q: What needs to be included in the "Current and Pending Support" section?
- A: Please submit a listing of all sponsored research support for the effort of the PI that is active or pending (submitted or awarded by a research sponsor but not yet started). Include the name of the title of the project, research sponsor, total annual funding, start and end dates, and percent of committed time. For each project, you <u>must</u> include a statement of overlap or non-overlap with the MRA proposal. A template is provided in proposalCENTRAL.
- Q: Is the NIH biosketch format acceptable for submission to MRA?
- A: Yes, MRA encourages you to use your NIH biosketch. You may also use the template provided in proposalCENTRAL.

ADDITIONAL INFORMATION AND CONTACTS

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Rachel Fischer Ph.D., MRA Senior Associate, Scientific Program and Grants Administration, at <u>rfischer@curemelanoma.org</u>.

Technical questions about the proposalCENTRAL submission system should be directed to their customer support at 800-875-2562 (Toll-free U.S. and Canada), +1 703-964-5840 (Direct Dial International) or by email at pcsupport@altum.com. Support is available from 8:30am-5pm Eastern Time, Monday through Friday.