

2017-2018 REQUEST FOR PROPOSALS SECOND RELEASE

September 8, 2017

The Melanoma Research Alliance (MRA) is pleased to announce its second Request for Proposals (RFP) for the 2017-2017 cycle focused on a **Special Opportunity Award jointly funded by The Rising Tide Foundation for Clinical Cancer Research (RTFCCR) and MRA**.

MRA's First Release RFP describing additional awards being offered this cycle was announced on August 14, 2017. For your convenience, the First Release RFP is appended at the bottom of this Second Release RFP in this Combined RFP. Interested applicants should refer to this First Release RFP for complete instructions on eligibility, key criteria, and instructions on how to apply for this and other MRA awards this cycle. An investigator may serve as PI on only one proposal submitted to MRA for any of the mechanisms in this cycle, including the RTFCCR-MRA award announced in this RFP, in the First Release RFP or in the American Cancer Society-MRA joint RFP: Understanding, Preventing and Managing Immunotherapy-Related Adverse Events (irAEs) Associated with Checkpoint Inhibition for Melanoma and Other Cancers. The deadlines for this Award are the same as for the Team Science Awards offered this cycle. MRA plans to award at least \$10 million for all awards announced during the 2017-2018 cycle.

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Kristen Mueller, Ph.D., MRA Scientific Program Director at kmueller@curemelanoma.org.

SPECIAL OPPORTUNITY AWARD FOR TEAM SCIENCE: RTFCCR-MRA European-led Team Science Award

Letters of Intent (LOIs) are due on October 6, 2017
Invited full length proposals from meritorious LOIs are due on January 9, 2018

The following Special Opportunity is for a Team Science Award, which is designed to foster a multidisciplinary, collaborative research process and promote transformational research advances with the potential for rapid clinical translation in prevention, early detection, staging and/or treatment of melanoma.

Multidisciplinary teams of two or more PIs led by an **Administrative PI at a European research institution** will receive up to \$900,000 USD total over 3 years, to support clinical research projects related to melanoma. Teams may include researchers located outside of Europe. Projects must include at least 50% of the budget focused on early stage clinical studies and/or clinical translational research that demonstrates potential for quick and meaningful impact. Basic research or phase IV clinical trials are not eligible for this award. Each team must also include at least one Young Investigator as a co-investigator.

Teams must consist of two or more established PIs and a Young Investigator with complementary expertise. The designated Administrative PI is responsible for administrative leadership. All PIs on the team share authority for scientific leadership. An investigator may serve as a PI, including Administrative PI and all collaborating PIs, on only one LOI. **Each team must include at least one Young Investigator as a co-investigator** (see and comply with all Young Investigator eligibility criteria in the First Release RFP

whose work must be integral to one or more of the aims of the proposal. An investigator may only be the designated Young Investigator on <u>one</u> proposal in the team science category. A designated Young Investigator on a team science application may also apply for a Young Investigator Award.

Team Science Awards have a collaborative and multidisciplinary emphasis, involving meaningful collaboration between participants. LOIs must include a description of the nature of and rationale for the proposed collaboration, the specific role of all PIs and the Young Investigator, and synergistic opportunities. Evidence of prior productive collaborations between members of the team is also useful.

Applicants should submit to the general Team Science Award program and designate their desire to be considered for this award when completing their online application in proposalCENTRAL. To do this, please make the "European-led Team" selection in the Title Page step of the on-line application. All Team Science Award submissions under the RFP that are European-led will automatically be made eligible for the RTFCCR-MRA award, unless the applicant opts out, The review and selection process for this European-led Team Science Award will be jointly conducted by RTFCCR and MRA. As such, both RTFCCR and MRA reviewers will have access to all proposals for this funding program. If selected for funding, awardee Administrative PIs 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.

The Switzerland-based RTFCCR aims to exert an indelible influence and support groundbreaking and pioneering clinical cancer research to help patients improve their quality of life and win the fight against cancer. MRA is pleased to partner with the Rising Tide Foundation for Clinical Cancer Research to advocate for early clinical research related to melanoma and to promote strategic research alliances around the globe.

2017-2018 REQUEST FOR PROPOSALS FIRST RELEASE

August 14, 2017

The Melanoma Research Alliance (MRA) is pleased to announce a Request for Proposals (RFP) for high-impact pre-clinical, translational, and early clinical research that has the potential to lead to near-term impact in melanoma prevention, detection, diagnosis, staging, and treatment. This cycle, proposals will be accepted for Team Science Awards, Young Investigator Awards, Academic-Industry Partnership Awards (for Established Investigators), and a Special Opportunity Award. This cycle, MRA plans to support at least \$9 million in new funding through this RFP with an additional \$1 million through the American Cancer Society-MRA joint RFP: Understanding, Preventing and Managing Immunotherapy-Related Adverse Events (irAEs) Associated with Checkpoint Inhibition for Melanoma and Other Cancers, which was announced separately.

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Introduction

About Melanoma: According to the National Cancer Institute, melanoma is the fifth most common cancer in the United States and rates continue to increase. 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 is a significant need for developing new treatment approaches, 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 \$88 million to support research projects worldwide. Please visit www.curemelanoma.org 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 melanoma patients). Successful proposals will offer the potential for translational development that could lead to high impact, near-term clinical application in melanoma detection, prevention, diagnosis, staging, 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 prevention strategies.
- **Detection, Diagnosis, and Staging:** Development of targeted screening methods and 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, combination therapies, and development of novel biomarkers of
 response to therapy.

Special Emphasis Areas: For the 2017-2018 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 scientific studies:

- 1. Addressing treatment failures or difficult-to-treat disease, which may include e.g. metastatic brain disease, rare melanoma subtypes, or non-BRAF-mutant melanomas such as NRAS or NF1-mutant melanoma by undertaking studies leading to new targets and/or rational treatment approaches.
- 2. Informing logical and optimal combination therapies, therapeutic sequences, or treatment regimens, including defining dose or duration of targeted and/or immunotherapies.
- 3. Developing markers of response, resistance, or risk of recurrence or death to improve decision-making and treatment, including research that accelerates the utility of adjuvant or neo-adjuvant therapies.
- 4. Identifying new targets, treatments, or biomarkers by leveraging data (e.g. clinical, genomics, and immunologic) that may include the study of exceptional responders/non-responders.

KEY REVIEW AND SELECTION CRITERIA

- Scientific merit: Outstanding and rigorous proposals as determined by peer review.
- Innovative, creative and transformative research: Novel approaches with strong scientific rationale and clear capacity to enhance prevention, detection, diagnosis, staging, or treatment for patients with melanoma or for individuals at risk are encouraged.
- **Potential for rapid progression to clinical testing:** Proposals that articulate a clear path to near-term clinical application will be strongly favored.

APPLICANT ELIGIBILITY

MRA encourages applications from a diverse pool of investigators. 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. 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. PIs must be able to show clear evidence of an independent research program. Fellows or those in other training or research support positions are not eligible. Individuals employed by state or federal government agencies may participate in research proposals as non-funded collaborators, but may not apply for MRA funding. If there are any questions about eligibility, please contact Tasheema Prince, MRA Scientific Program Manager, at tprince@curemelanoma.org before submitting an application. Applications from PIs who do not meet the eligibility criteria will not be reviewed.

An investigator may serve as PI on only one proposal submitted to MRA for any of the award mechanisms in this cycle. This includes all PIs except Young Investigators on Team Science Awards and includes any Special Opportunity Awards described in this RFP and in separate announcements released during the 2017-2018 cycle (including any applicants submitting a full proposal to the American Cancer Society-MRA RFP). Multiple applications will be accepted from a single institution, provided that each application has a different PI and represents a distinct hypothesis.

Types of Awards

AWARDS FOR TEAMS

Letters of Intent (LOIs) are due on October 6, 2017
Invited full length proposals from meritorious LOIs are due on January 9, 2018

MRA TEAM SCIENCE AWARDS

Awards for team science are designed to foster a collaborative research process and promote transformational melanoma research advances with the potential for rapid clinical translation. Multidisciplinary teams of two or more established Principal Investigators and a Young Investigator with complementary expertise will receive up to \$900,000 total over 3 years, to support projects with the potential to lead to transformative advances in prevention, detection, diagnosis, staging and/or treatment of melanoma.

Teams may consist of investigators from the same institution, or different institutions, and may be international. The designated Administrative PI is responsible for administrative leadership. All PIs in the team share authority for scientific leadership. An investigator may serve as a PI, including Administrative PI and all collaborating PIs, on only one LOI and invited proposal. **Each team must include at least one Young Investigator as a co-investigator**, whose work must be integral to one or more of the aims of the proposal (see and comply with all Young Investigator eligibility criteria below). An investigator may only be the designated Young Investigator on <u>one</u> application in the Team Science Award category. However, a Young Investigator identified within a Team Science Award application may also apply in the same cycle for their own, individual Young Investigator Award.

Team Science Awards have a collaborative and multidisciplinary emphasis, involving meaningful collaboration between participants. LOIs must include a description of the nature of and rationale for the proposed collaboration, the specific role of all PIs and the Young Investigator, and synergistic opportunities derived from the team proposed. Evidence of prior productive collaborations between members of the team is also useful.

AWARDS FOR YOUNG INVESTIGATORS

Full proposals are due on November 17, 2017. No LOI is required under Young Investigator Awards

Young Investigator Awards aim to attract early career scientists with novel ideas into the field of melanoma, thereby recruiting and supporting the next generation of melanoma research leaders. Awardees will be provided up to \$75,000 per year for three years (up to \$225,000 total) to accomplish innovative and creative, preclinical, translational, and/or early clinical research projects.

Applicants must be within four years of their first independent, full time academic faculty appointment at the time of application at the level of Assistant Professor (or equivalent position). Applicants need not be on a tenure-track; however, fellows or others who are in training are not eligible to apply. Those who are in research support positions are not eligible to apply. Applications from those who have secured an independent full-time faculty position commencing by July 1, 2018 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. Any applicant not expected to hold an Assistant Professor position (e.g., Instructor or other title) by July 1, 2018 must contact MRA to confirm eligibility prior to submitting a proposal. To confirm eligibility, interested applicants must send an email, along with their biosketch, to Tasheema Prince, MRA Scientific Program Manager, at tprince@curemelanoma.org by November 10, 2017. Investigators who have been awarded a prior MRA Young Investigator Award are not eligible to apply for an additional MRA Young Investigator Award.

Young Investigator applicants must designate 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. A support letter from the Mentor must be included in the application package and 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.

SPECIAL OPPORTUNITY: MRA YOUNG INVESTIGATOR AWARD FOR WOMEN IN SCIENTIFIC RESEARCH

Full proposals are due on November 17, 2017. No LOI is required under Young Investigator Awards

MRA is proud to offer a Young Investigator Award with the goal of attracting and supporting early career female researchers who are conducting cutting-edge melanoma research. The awardee will receive up to \$225,000 total over 3 years to support projects with the potential to lead to transformative advances in prevention, detection, diagnosis, staging or treatment of melanoma. For this Award, the PI must be a woman.

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 make the "Woman Young Investigator" selection under subprogram in the Title Page step of the online application. One award will be funded via this Special Opportunity, but as is our practice, MRA will grant additional Young Investigator Awards regardless of the gender of the applicants. Selecting "Woman Young Investigator" will not limit an applicant's opportunity to also be selected under general Young Investigator Awards, but instead is meant to expand opportunities in an effort to increase overall the number of women competing for funded research.

ESTABLISHED INVESTIGATOR ACADEMIC-INDUSTRY PARTNERSHIP AWARDS

Full proposals are due on November 17, 2017. No LOI is required under Established Investigator Academic-Industry Partnership Awards

These awards are 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 co-funded by MRA and an industry partner whose involvement is essential to the project. Investigators with an established record of scientific productivity will receive up to \$100,000 per year for two to three years (up to \$300,000 total) from MRA to conduct projects supported by preliminary data.

Industry funds and/or in-kind support (e.g., reagents, clinical grade drugs, equipment, and contract services) must match but may exceed MRA funds for the award period. Industry scientists may serve as co-investigators or collaborators, but may not be PIs. Non-contract industry personnel costs may not be counted as in-kind support. 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.

Applications must include a letter of support from the industry partner, which should include at a minimum the following: 1) 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 be at least 50% of the total support for the project); and 2) acknowledgement that if the award is made the industry partner will execute agreements with both MRA and the awardee Institution within 90 days.

Industry Partners must contact Kristen Mueller, MRA Scientific Program Director, at kmueller@curemelanoma.org by November 10, 2017, to discuss the terms of the partnership agreement. All other questions regarding the award should be directed to Tasheema Prince, Scientific Program Manager, at tprince@curemelanoma.org.

APPLICATION FORMAT AND INSTRUCTIONS

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 https://proposalcentral.altum.com/ and the document templates and requirements therein. Please carefully follow the instructions in proposalCENTRAL and below. Applications include the following steps and components:

TEAM SCIENCE AWARDS

Letters of Intent are due on October 6, 2017; invited full proposals are due Jan 9, 2018

Applicants must submit a one-page letter of intent (LOI) to MRA prior to submission of a full proposal. **Please carefully follow the instructions in proposalCENTRAL.** The LOI application consists of the following components:

- 1. **Title Page:** Enter the project title.
- 2. **Applicant/PI Information:** Team Science applications must identify one PI for administrative purposes (the Administrative PI for the proposal). This is the Applicant.
- 3. **Organization/Institution Information:** This is the Administrative PI's institution.

- 4. **Key Personnel Information:** Identify other PIs on the team as well as the Young Investigator and their Mentor. All PIs share authority for project leadership. The position of "co-PI" is not offered under this mechanism.
- 5. Letter of Intent: One page maximum that includes a) a description of the scientific aims and translational potential; and b) the nature of and rationale for the proposed collaboration, the specific role of each participant, and synergistic opportunities. Letters exceeding the one-page limit will not be considered.

Full length applications will be invited from meritorious LOIs. They must be prepared according to the following instructions and according to instructions in proposalCENTRAL, and will be due on **January 9**, **2018**. The application consists of the following components:

- 1. **Title Page:** Enter the project title. For proposals involving multiple institutions, please include a total amount requested for each institution in the designated spaces provided.
- 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. This <u>must</u> be the Administrative PI on team science applications.
- 5. **Organization/Institution:** Key information about the Applicant/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.
- Key Personnel: List and provide contact information for key persons. Include all PIs on the proposal as well as any additional key personnel. A designated Young Investigator and their Mentor is required.
- 7. **Abstracts and Keywords:** Provide a lay audience friendly abstract and a technical abstract (2,000 characters maximum each) and key words. <u>Please note</u>: the lay abstract will become public if the award is selected for funding, therefore it should not contain any proprietary information.
- 8. **Budget Period Detail:** Enter budget detail for each award period requested. **MRA will not support indirect costs, overhead costs, or other similar institutional levies.** Fringe benefits for personnel salaries are allowable.
- 9. Budget Summary and Justification: A summary of the budget detail will be shown. 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 # 11. For proposals involving more than one institution: Do not include partner institution costs under contract costs; this category should only be used for contracts with outside facilities for performance of services.

- 10. **Organizational Assurances:** IRB and IACUC approvals, if applicable.
- 11. Upload Attachments: Upload the following:
 - a. **Biosketch for PIs, Young Investigator, and other key personnel:** Applicants may use the template provided or the NIH biosketch format.
 - b. Current and pending research support for the PIs and Young Investigator: Use the template provided in proposalCENTRAL, which includes a statement of overlap. Any overlap of current or pending support with the MRA 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. 5 pages maximum, inclusive of the following: Background and specific aims, preliminary data, experimental design and methods, figures (which may be embedded within the above sections), and rationale/fit with key criteria, including the potential for clinical impact.
 - d. **Scientific references:** A list of up to 20 references supporting the project description is allowed, in addition to the 5-page project description.
 - e. Young Investigator Mentor Letter: Include a letter of support from an established scientific Mentor at the <u>same institution</u>, who is familiar with the Young Investigator and his/her work and will provide guidance and support for the project. The Mentor's letter should confirm that the Young Investigator has an independent research program and include a brief statement about the Young Investigator, the Mentor's role, mentoring plan, the research environment, core facilities, and other sources of institutional support (monetary or in-kind) which 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: http://www.csw.arizona.edu/sites/default/files/csw 2015-10-20 Jorbias pdf 0.pdf
 - f. **For clinical trials proposals:** Attach a brief protocol synopsis (no longer than 5 pages), along with a <u>timeline and milestones</u>, including but not limited to IRB and regulatory approval (if applicable), patient accrual timeline, and timeline for completion of analyses.
 - g. **For multi-institutional proposals:** Attach a letter from the Administrative PI's institution confirming that if the award is made, the institution will execute the necessary sub-award agreements within 60 days of execution of the award agreement between MRA and the applicant institution and will transfer funds from their institution to the collaborating institution(s). When uploading in proposalCENTRAL, select "Inter-Institutional Team Funding Letter."
- 12. Validate: Check for any missing required information.
- 13. **Signature pages:** Print the signature page, which must be signed by the PI and the institution's signing official, and uploaded as part of the application package.

14. **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.

YOUNG INVESTIGATOR AWARDS AND ACADEMIC-INDUSTRY PARTNERSHIP AWARDS

Complete applications are due on November 17, 2017

- 1. Title Page: Enter the project title
- 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 <u>Young Investigator</u> Award applicants, a Mentor from the same institution is required
- 7. **Abstracts and Keywords:** Provide a general audience abstract (non-technical) and a technical abstract (2,000 characters maximum each) and key words. <u>Please note</u>: the general audience abstract will become public if the award is selected for funding, therefore, it should not contain any proprietary information.
- 8. **Budget Period Detail:** Enter budget detail for each award period requested. **MRA will not support indirect costs, overhead costs, or other similar institutional charges.** Fringe benefits for personnel salaries are allowable. <u>Academic-Industry Partnership Award proposals</u> should contain the complete budget for the project, which includes both the MRA and industry partner contributions (direct costs only).
- 9. 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 # 11. For Academic-Industry Partnership Award proposals: The amount of funding anticipated solely from MRA must be clearly indicated in the Budget Justification.
- 10. **Organizational Assurances:** IRB and IACUC approvals, if applicable.
- 11. Upload Attachments: Upload the following:
 - a. **Biosketch for PI and key personnel:** Applicants may use the template provided or the NIH biosketch format.

- b. **Current and pending research support for the PI:** Use the template provided in proposalCENTRAL, which includes a statement of overlap. <u>Any overlap of current or pending support with the MRA proposal must be described and explained.</u>
- 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: Background and specific aims, preliminary data, experimental design and methods, figures (which may be embedded within the above sections), and rationale/fit with key criteria, including the potential for clinical impact.
- d. **Scientific references:** A list of up to 20 references supporting the project description is allowed, in addition to the 5-page project description
- e. For Young Investigator Award proposals: Include a letter of support from an established scientific Mentor at the <u>same institution</u>, 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:
 - http://www.csw.arizona.edu/sites/default/files/csw_2015-10-20_lorbias_pdf_0.pdf
- f. **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 be at least 50% of the total support for the project)
 - 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 Tasheema Prince, MRA Scientific Program Manager at tprince@curemelanoma.org.
- g. For proposals involving clinical trials: Attach a brief protocol synopsis (5 pages maximum), along with a <u>timeline and milestones</u>, including but not limited to IRB and regulatory approval (if applicable), patient accrual timeline, and timeline for completion of analyses
- 12. **Validate:** Check for any missing required information
- 13. **Signature Page(s):** Print the signature page, which must be signed by the PI and the institution's signing official, and uploaded as part of the application package
- 14. **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.

TIMELINE

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

- October 6, 2017: Team Science Award Letters of Intent are due
- November 10, 2017: For Young Investigators: Deadline to confirm eligibility with MRA for those applicants that do not have Assistant Professor titles
- November 10, 2017: Deadline for Industry partners to contact MRA to discuss Award Terms and Conditions
- **November 17, 2017:** Young Investigator Award and Academic-Industry Partnership Award proposals are due
- Mid-November 2017: Teams from meritorious LOIs are invited to submit full length proposals
- January 9, 2018: Full length proposals for Team Science Awards are due
- Late February/Early March 2018: Peer and organizational review
- Late March/Early April 2018: Awardees notified (Note that MRA may adjust the notification date without notice to applicants)
- May 2018: 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. Applications will be scored according to MRA Key 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 Please contact Tasheema Prince, MRA Scientific request. Program Manager, tprince@curemelanoma.org. All awards are contingent upon ratification by the MRA Board of Directors. MRA will make every effort to provide brief, written reviewer feedback to all applicants. A listing of GRC membership and descriptions of the projects funded in 2008-2017 are provided on our website, www.curemelanoma.org.

COLLABORATIVE FUNDING OFFERS

For outstanding research proposals as determined by peer review that fall beyond MRA's funding payline, MRA may seek co-funding from applicant institutions in order to support these proposals. MRA will reserve \$1 million of its support for the Collaborative Funding program this cycle. For our Collaborative Funding program, MRA will: (a) provide one third of the award funds for Young Investigator and Academic-Industry Partnerships Awards made under this program and each PI's institution will provide the remaining two thirds of the relevant budget for that institution; and; (b) for Team Science Awards, MRA will provide one half of the award funds and each institution represented on the award application will provide one half of their budget. All institutions must provide their half of the funding for MRA to collaboratively fund a Team Science Award. In case of questions, please contact Tasheema Prince, MRA Scientific Program Manager at tprince@curemelanoma.org.

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 https://www.curemelanoma.org/assets/Uploads/PDFs/TermsAndConditions2018.pdf. MRA must be notified in advance and approve of any significant changes in research objectives, key personnel (including transfer to another employee), or budget. For Academic-Industry Partnership Awards, the industry partner will be required to sign a letter of agreement with MRA, the institution will be required to sign the Award Letter with MRA, and the institution must finalize their contract with the industry partner all within 90 days.

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. MRA will not support indirect costs, overhead costs, 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 and, in the case of Academic-Industry Partnership Awards, industry partners 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.

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 is not required. Evidence of independent investigator status and an environment conducive and supportive of translational 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. Young Investigator applicants who do not hold an Assistant Professor title must contact MRA to verify their eligibility prior to submitting a proposal (see additional FAQs for Young Investigators below).
- 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. Pls 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. Please note that the ACS-MRA RFA, which was announced separately, is limited to U.S. applicants only.
- 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: https://orcid.org/register. More information about ORCID IDs can be found here: https://orcid.org/.
- Q: Why is MRA collecting demographic information?
- A: MRA now 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 inequities that exist in the selection process.

Young Investigator Awards

- Q: I will be past the first four years of my first faculty appointment at the time the project starts. May I apply to the Young Investigator Award?
- A: Applicants should be within the first four years of their first faculty appointment at the time of proposal submission.
- 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).
- 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 Award 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 will not be considered a Mentor for the award.
- Q: Are Mentors of Young Investigator Award applicants allowed to be a PI of an existing MRA award or award application this cycle?
- A: Yes.
- 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.

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 industrial 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 industrial 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 will be considered for MRA's Collaborative Funding Program. The collaborative funding process will be conducted after the scientific review process has been completed.

- Q: Must every institution with key personnel on a Team Science Award or Academic-Industry Partnership Award participate in collaborative funding?
- A: Yes. Each institution represented in the award budget must provide one-half of their approved budget for Team Science Awards or two-thirds of their approved budget for Academic-Industry Partnership Awards in the Collaborative Funding Program.

Application components

- Q: How are proposals submitted? Do I need to send a hard copy?
- A: All proposals must be submitted electronically via proposalCENTRAL, https://proposalcentral.altum.com. The signature page should be signed and a scanned PDF copy be uploaded as part of the application in proposalCENTRAL. Hard copies will not be accepted.
- 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, you may use your NIH biosketch or the template provided in proposalCENTRAL.

Submitting research proposals that address immunotherapy-related adverse events (irAEs)

- Q: Can I submit an LOI or other proposal that addresses irAEs under this RFP?
- A: Yes. However, an investigator submitting a full proposal under the American Cancer Society-MRA RFP: Understanding, Preventing and Managing Immunotherapy-Related Adverse Events (irAEs) Associated with Checkpoint Inhibitions for Melanoma and Other Cancers is not eligible to submit for this RFP.

Additional Information and Contacts

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Tasheema Prince, MRA Scientific Program Manager at tprince@curemelanoma.org.

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.