

## Melanoma Research Alliance 2013-2014 REQUEST FOR PROPOSALS

Melanoma is a leading cause of new cancers, and more effective options for patients and those at risk are urgently needed. Recent scientific and clinical advances have provided new options, but much work remains to be done in the areas of early detection, prevention, diagnosis, and to optimize the effectiveness of existing and emerging treatments. From a basic and clinical research perspective, melanoma occupies the crossroads of molecular biology and immunology. Cutaneous melanomas can be queried at the earliest stages of carcinogenesis for molecular events or signatures predicting progression, invasion and dissemination. As perhaps the most highly immunogenic human tumor, melanoma also provides an ideal context for understanding interactions between the human immune system and cancer. The Melanoma Research Alliance (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. MRA is poised to build on recent momentum in the field, accelerating the pace of scientific discovery and translation in order to eliminate suffering and death due to melanoma. To date the MRA has awarded more than \$48 million to research projects worldwide. Please visit <http://www.curemelanoma.org> for further information on MRA and the research projects funded in prior award cycles.

### OBJECTIVE: EMPHASIS ON TRANSLATIONAL SCIENCE

The 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. Proposals will be accepted for Young Investigator Awards, Established Investigator Academic-Industry Partnership Awards, Team Science Awards, and Special Opportunity Awards. 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 investigations testing well defined and clearly articulated hypotheses are welcome and should be accompanied by a brief protocol synopsis; local IRB approval is not required at the time of application but is required in order to grant the award. MRA plans to support at least \$8 million in new funding during the 2013-2014 cycle.

### MRA welcomes proposals in the following areas:

- **Prevention:** Elucidation of environmental, epidemiological and biological factors in melanoma carcinogenesis.
- **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 are solicited. 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 2013-2014 cycle, proposals in the following areas are of particular interest and will receive special consideration. These can include pre-clinical, clinical, and/or correlative scientific studies.**

- Undertaking studies of novel combination therapies involving immunotherapy.
- Identifying and overcoming resistance mechanisms to BRAF/MEK combination targeted therapy.
- Identifying biomarkers predictive of clinical outcomes to treatment regimens, both approved and investigational, which may include studies of the tumor microenvironment, invasion, and metastasis.
- Improving the understanding of the biological basis for melanoma formation, such as risk factors and the interaction of risk and the environment, in order to develop better prevention and early detection strategies.

### **KEY CRITERIA**

- **Innovative and transformative research:** Novel approaches with strong scientific rationale and clear capacity to revolutionize prevention, early diagnosis, staging, or treatment for patients with melanoma or for individuals at risk are encouraged.
- **Scientific merit:** Outstanding and rigorous proposals as determined by peer review.
- **Potential for rapid progression to clinical testing:** Proposals that articulate a clear path to near-term clinical application will be strongly favored.
- **Additional Key Criterion for Team Science Awards - Collaborative and multidisciplinary emphasis:** Meaningful collaboration between two or more PIs with complementary expertise that offers the possibility for synergistic advances. Research groups may be within the same institution, or inter-institutional.

### **ELIGIBILITY**

**Principal Investigators (PIs) must hold a faculty appointment at an academic research institution** within or outside the United States at the level of **Assistant Professor (or equivalent) or above**. 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 federal government agencies may participate in research proposals as non-funded collaborators, but may not apply for direct funding. If there are any questions about eligibility, please contact the MRA before submitting an application. Applications from PIs who do not fit the eligibility criteria will not be reviewed.

**An investigator may serve as PI on only one proposal submitted to the MRA under any of the mechanisms in this cycle.** 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

Additional information is provided under the Application Format and Due Dates section below.

### **MRA TEAM SCIENCE AWARDS**

**Letters of Intent (LOIs) are due on Monday, October 7, 2013**

Multidisciplinary teams of two or more PIs will receive up to \$1 million total over 2 to 3 years, to support projects with the potential to lead to transformative advances in prevention, early detection, staging and/or treatment of melanoma. All PIs in the team share authority for scientific leadership. The designated Administrative PI is responsible for administrative 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 below), whose work must be integral to one or more of the aims of the proposal.

### **SPECIAL OPPORTUNITY: SABAN FAMILY FOUNDATION-MRA TEAM SCIENCE AWARDS**

**Full length proposals are due on Monday, October 14, 2013**

Multidisciplinary teams of two or more Principal Investigators (PIs) led by an **Administrative PI at a research institution in Israel** will receive up to \$1 million USD total over 2 to 3 years, to support projects with the potential to lead to transforming advances in prevention, early detection, staging and/or treatment of melanoma. Up to two teams may be funded.

PIs may be from the same institution or different institutions and may include PIs or other key personnel from institutions outside of Israel. Each team must include at least one Young Investigator as a co-investigator who is at an institution in Israel (see and comply with all Young Investigator eligibility criteria above), whose portion of the project work must be integral to one or more of the aims of the proposal. An investigator may participate in two proposals; however, an investigator may only serve as a PI on one proposal in response to this Special Opportunity. Each institution may submit no more than two proposals with an Administrative PI from that institution.

Applicants for this opportunity should follow the instructions on full length Team Science Award proposals (below); no Letters of Intent are required. Review of submitted proposals will be done on an accelerated timeframe by members of MRA's Grant Review Committee. Applicants will be notified of MRA's decision in December 2013. Awarded research projects will be expected to begin by February 1, 2014.

Please contact MRA (contact information at the end of this RFP) with any questions about this Special Opportunity. Proposals that are incomplete or do not follow MRA's guidelines will not be considered.

## **MRA YOUNG INVESTIGATOR AWARDS**

**Proposals are due on Wednesday, November 13, 2013**

Investigators within 4 years of their first academic faculty appointment at the time of application will be provided up to \$75,000 per year for 3 years to accomplish innovative, translational research projects. Young Investigator applicants must designate a Mentor, i.e., a senior investigator at the same institution who will ensure that adequate support and guidance are provided for successful completion of the proposed research project. Fellows or others who are in training or support positions are not eligible to apply. However, applications from those who have secured an independent faculty position commencing by July 1, 2014 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.

## **MRA ESTABLISHED INVESTIGATOR ACADEMIC-INDUSTRY PARTNERSHIP AWARDS**

**Proposals are due on Wednesday, November 13, 2013**

These awards are designed to facilitate progress via interactions between the academic and industrial research sectors, and will be co-funded by MRA and an industrial collaborator whose involvement is essential to the project. The PI must be an academic investigator. Investigators with an established record of scientific productivity will receive up to \$100,000 per year for 2 to 3 years from MRA to conduct projects supported by preliminary data. Industry funds and/or in-kind support (e.g., reagents, clinical grade drugs, equipment, 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.

Industry will negotiate contract terms directly with the awardee'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, a finalized contract between industry and the institution is required within 90 days of the award date, barring extenuating circumstances, before funds can be dispensed, or MRA may withdraw its offer of award. To insure timely sharing of new findings, industry's contract stipulations for corporate review of scientific presentations may not exceed 30 days for review of new manuscripts, or 14 days for review of slide presentations for major conferences, barring extenuating circumstances. Standard contract clauses developed by the CEO Roundtable on Cancer in conjunction with NCI may provide helpful guidance for streamlining contract negotiations (<http://ceo-lsc.org/TaskForceScrape.aspx>). For successful applications, a letter of commitment will be required from industry to MRA to support the project for the full term of the award.

## **APPLICATION FORMAT AND INSTRUCTIONS**

Applicants must utilize the proposalCENTRAL on-line application tool at <http://proposalcentral.altum.com> and the document templates and requirements therein. Please carefully follow the instructions in proposalCENTRAL. All applications must be formatted in Arial 11 point or Times New Roman 12 point font with no less than ½ inch margins. Proposals submitted after the deadline will not be considered.

## MRA TEAM SCIENCE AWARDS

**Letters of Intent: Due on Monday, October 7, 2013 at 5:00 p.m. Eastern Time**

Applicants must submit a one-page letter of intent (LOI) to MRA prior to submission of a full proposal (this does not apply to the Saban Family Foundation-MRA Team Science Award Special Opportunity). **Please carefully follow the instructions in proposalCENTRAL.** The LOI consists of the following components:

- Applicant/PI information: Team Science applications must identify one PI for administrative purposes (the Administrative PI for the proposal). This is the Applicant.
- Organization/institution information: This is the Administrative PI's institution.
- Key personnel information: Identify other PIs and key personnel on the team. All PIs share authority for project leadership. The position of "co-PI" is not offered under this mechanism.
- Letter of intent: **One page maximum** that includes a description of the scientific background, aims, research plan and translational potential; the nature of and rationale for the proposed collaboration, and the role of each participant; and synergistic opportunities. **Letters exceeding the one-page limit will not be considered.**
- Signature page: **An investigator may serve as a PI, including Administrative PI or collaborating PI, on only one LOI.** Using the template provided, all PIs (including the Administrative PI and collaborating PIs) must sign a form verifying that none of the PIs are PIs on other MRA LOIs.

**Full length proposals:** MRA Team Science Award full length proposals are invited by MRA from meritorious LOIs. Invited full proposals will be due on **Monday, January 13, 2014. Saban Family Foundation-MRA Team Science Award** full length applications are due on **October 14, 2013 (LOIs are not required).**

Complete Team Science Award applications include the following components, which are generated as part of the proposalCENTRAL system:

- Applicant/PI information
- Organization/institution information
- Key personnel information (Young Investigators participating in Team Science Award applications, must designate a Mentor from their same institution and include a Mentor letter in the application)
- Lay abstract and technical abstract (250 words maximum each) and key words. **Please note:** the lay abstract will become public if the award is selected for funding, therefore it should not contain any proprietary information.
- Budget details and justification: **MRA will not support indirect costs, overhead costs, or other institutional levies.** Fringe benefits for personnel salaries are allowable. Organizational assurances: IRB and IACUC approvals, if applicable
- **Curriculum vitae for PIs and key personnel:** Applicants may use the template provided or the NIH biosketch format
- Current and pending research support for PIs: Use the template provided in proposalCENTRAL, which includes a statement of overlap. **Any overlap of current or pending support must be described and explained.**
- Project Description: **5 pages maximum**, inclusive of the following: Background/specific aims, preliminary data, experimental design and methods, and rationale/fit with key criteria, including a description of the potential for clinical impact with milestones (if applicable).

- Literature references: a list of up to 20 references supporting the project description is allowed, in addition to the 5-page project description.
- For Young Investigators: 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 include a brief statement about the research environment, core facilities, and other sources of institutional support (monetary or in-kind) which the applicant will utilize in conducting the project.
- Clinical trials proposals: Attach a brief protocol synopsis (no longer than 5 pages).

## **YOUNG INVESTIGATOR AWARDS AND ESTABLISHED INVESTIGATOR ACADEMIC-INDUSTRY PARTNERSHIP AWARDS**

**Complete applications are due on Wednesday, November 13, 2013 at 5:00 p.m. Eastern Time.** In contrast to the Team Science application requirements described above, letters of intent to MRA are **not** part of this application process.

Applications include the following components, which are generated as part of the proposalCENTRAL system:

- Applicant/PI information
- Organization/institution information
- Key personnel information (Young Investigator Award applicants must designate a Mentor from their same institution and include a Mentor letter in the application)
- Lay abstract and technical abstract (250 words maximum each) and key words. **Please note:** the lay abstract will become public if the award is selected for funding, therefore it should not contain any proprietary information.
- Budget details and justification: **MRA will not support indirect costs, overhead costs, or other institutional levies.** Fringe benefits for personnel salaries are allowable. Established Investigator Academic-Industrial Partnership Award proposals should contain the complete budget for the project, which includes both the MRA and partner contributions (direct costs only). In addition, the amount of funding anticipated solely from MRA must be **clearly indicated** in the Budget Justification.
- Organizational assurances: IRB and IACUC approvals, if applicable
- Curriculum vitae for PI and key personnel: Applicants may use the template provided or the NIH biosketch format
- Current and pending research support for the PI: Use the template provided in proposalCENTRAL, which includes a statement of overlap. **Any overlap of current or pending support must be described and explained.**
- Project Description: **5 pages maximum**, inclusive of the following: Background/specific aims, preliminary data, experimental design and methods, and rationale/fit with key criteria, including a description of the potential for clinical impact with milestones (if applicable).
- Literature references: a list of up to 20 references supporting the project description is allowed, in addition to the 5-page project description.
- For Young Investigators only: 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 include a brief statement about the research environment, core facilities, and other sources of institutional support (monetary or in-kind) which the applicant will utilize in conducting the project.

Applications demonstrating matching institutional support for MRA funds will receive special consideration.

- For Academic-Industrial Partnership Awards: Include a non-binding letter of support from the corporate partner to negotiate a contract with the awardee's Institution and to provide at least 50% support for the project, monetary (direct costs only) or in-kind, if the award is granted by MRA. Please include the proposed type and amount of matching support to be provided. For successful applications, a letter of commitment will be required from industry to MRA, to support the project for the full term of the award.
- Clinical trials proposals: Attach a brief protocol synopsis (no longer than 5 pages).

## SUMMARY OF TIMELINE

### MRA TEAM SCIENCE AWARDS

Note that MRA may adjust the notification dates without notice to applicants

- October 7, 2013: Letters of Intent due
- Late November, 2013: LOI applicants notified
- January 13, 2014: Invited full length proposals due
- Late February/Early March, 2014: Peer and organizational review
- Late March, 2014: Awardees notified
- May 1, 2014: Projects start

### SABAN FAMILY FOUNDATION-MRA TEAM SCIENCE AWARDS

Note that MRA may adjust the notification dates without notice to applicants

- October 14, 2013: Full proposals due
- Late November-Early December, 2013: Peer review and organizational review
- Mid-to-late December, 2013: Awardees notified
- February 1, 2014: Projects start

### MRA YOUNG INVESTIGATOR AWARDS AND MRA ACADEMIC-INDUSTRY PARTNERSHIP AWARDS

Note that MRA may adjust the notification dates without notice to applicants

- November 13, 2013: Full length proposals due
- Late February/Early March, 2014: Peer and organizational review
- Late March, 2014: Awardees notified
- May 1, 2014: 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 the Key Criteria listed above. All Awards are contingent upon ratification by the MRA Board of Directors. **MRA will not provide reviewer critiques or evaluations to applicants, with the exception of Young Investigator applicants; Young Investigator applicants whose proposals are discussed by the MRA GRC will receive brief commentary.** A listing of GRC membership and descriptions of the projects funded in 2008-2013 are provided on our website, <http://www.curemelanoma.org>.

## 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 (copy available in advance upon request). MRA must be notified in advance and approve of any significant changes in research objectives, key personnel, or budget. For Established Investigator Academic-Industry Partnership Awards, the partnering company will be required to sign a letter agreement with MRA (a copy available in advance upon request).

### 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. Failure to secure such approvals 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.

### 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 institutional levies**; 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 meeting certain milestones and deliverables, including submission of complete and accurate progress reports.

### MRA SCIENTIFIC RETREAT

PIs and, in the case of Academic-Industry Partnership Awards, corporate sponsors will be invited to attend the annual MRA Scientific Retreat. PIs are expected to attend and will be asked to present research findings made under their awards at these meetings.

## FREQUENTLY ASKED QUESTIONS

### Eligibility

- Q: Must PIs have an academic faculty appointment? Is this a hard-and-fast rule?
- A: PIs must have a faculty appointment at an academic research institution; however, while a tenure-track is preferred, it 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 the MRA (contacts provided below) before an application is submitted. Applications from PIs who do not fit the eligibility criteria will not be reviewed.
- Q: I am a Fellow at an academic institution. Am I eligible to apply for the Young Investigator Award?
- A: No. Those in training positions are not eligible. Only those with a faculty appointment will be considered.
- Q: Does MRA fund investigators and institutions outside of the United States?
- A: Yes. Investigators at institutions outside of the United States are eligible. PIs must be at the level of Assistant Professor or equivalent. Academic appointments of institutions outside of the U.S. can differ from those traditionally found in the U.S. Contact the MRA if there are any questions about eligibility prior to submitting a proposal.

### Young Investigator Awards

- Q: I will be past the first 4 years of my first faculty appointment at the time the project starts. May I apply to the Young Investigator Award?
- A: As long as you are within the first 4 years of your faculty appointment at the time of application, you are eligible to apply as a Young Investigator.
- Q: I would like to have a Mentor that is not at my institution. Is this allowed?
- A: All Young Investigator Award applicants must have a designated Mentor at their institution whose role is to help to ensure that the Young Investigator has the resources they need to successfully carry out the work at their institution. However, an applicant may designate two Mentors to include a senior investigator outside of their institution for other purposes, including providing scientific guidance for the project.

### Team Science Awards

- Q: What is the format of the Letter of Intent (LOI)?
- A: The format of the LOI is a one page document that includes a description of the scientific aims and translational potential, 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.** The LOI should be in PDF format and can be uploaded as an attachment on the proposalCENTRAL online application tool-- <https://proposalcentral.altum.com/>. MRA will not accept LOIs via email.
- Q: For Key Personnel, I notice there is no "Co-PI" role available? Why not?
- A: Team Science Awards are multiple PI programs, and all PIs are designated as such. Therefore, please do not enter "Co-PI" as a designation for any of the key persons. The Administrative PI is responsible for administrative aspects of the project.

- Q: What needs to be included in the inter-institutional team funding letter?  
A: For teams involving more than one institution, a letter from the Administrative PI's institution must be included that verifies that the institution will execute the necessary sub-award(s) and transfer funds to the collaborating institution(s).
- Q: I would be considered a Young Investigator by MRA eligibility standards (within the first 4 years of my first faculty appointment). May I serve as the Administrative PI or a collaborating PI on a Team Science Award?  
A: No. Investigators who are within the first 4 years of their first faculty appointment are eligible to serve as the designated Young Investigator as part of the team, not as the Administrative PI or collaborating PI.
- Q: Can a Young Investigator who is part of a Team Science Award also apply for a MRA Young Investigator Award?  
A: Yes, but only if the project represents a distinct hypothesis and is non-overlapping.
- Q: Can the Young Investigator be from a different institution than the Administrative PI?  
A: Yes, as long as the Young Investigator designates a Mentor from the same institution as part of the team. The Mentor can also serve as a PI or other key person on the project.
- Q: Am I allowed to be a PI of an award and a Mentor of a Young Investigator?  
A: Yes.
- Q: Is there a minimum level of effort for the Mentor?  
A: No.

### **Saban Family Foundation-MRA Team Science Awards**

- Q: Can you explain the rule about an institution having a maximum of two applications?  
A: Each Israeli institution may be named on a maximum of two proposals as the Administrative PI's institution.
- Q: I am an investigator at an Institution outside of Israel. May I be the Administrative PI for this Award?  
A: No. You may be a collaborating PI; however, the Administrative PI must be at an institution in Israel.

### **Established Investigator Academic-Industrial 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.
- Q: In the Partnership application budget, do I itemize expenses associated with only the request from the 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. 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.

## Application components

- Q: How are proposals submitted? Do I need to send a hard copy?
- A: All proposals must be submitted electronically via proposalCENTRAL, <http://proposalcentral.altum.com>. The signature page should be signed and a scanned PDF copy be uploaded as part of the application in PC. 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.
- 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(s) 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 must include a statement of overlap or non-overlap with the MRA proposal. A template is provided in proposalCENTRAL.
- Q: Is the NIH biosketch CV format acceptable for submission to MRA?
- A: Yes, you may use your NIH biosketch or the template provided in proposalCENTRAL.

## ADDITIONAL INFORMATION AND CONTACTS

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Laura Brockway-Lunardi, PhD, MRA Scientific Program Director at [lbl@curemelanoma.org](mailto:lbl@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](mailto:pcsupport@altum.com).