



## **Melanoma Research Alliance 2012-2013 REQUEST FOR PROPOSALS**

Melanoma is a leading cause of new cancers, and more effective options for early detection, prevention, diagnosis, and treatment are urgently needed. Recent scientific and clinical advances have provided new options for patients and those at risk, but much work remains to be done. 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 \$38 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, Academic-Industrial 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 \$7 million in new funding during the 2012-2013 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. 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 2012-2013 cycle, proposals in the following areas are of particular interest and will receive special consideration:**

- Developing rational combinatorial treatment regimens for patients with advanced unresectable melanoma, based on preclinical models. Defining mechanistic interactions among and between molecularly targeted and immune-based therapies.
- Identifying biomarkers for melanoma detection, prognosis, and prediction of response to approved and investigational therapies.
- Developing adjuvant and neoadjuvant melanoma therapies.
- Identifying and characterizing novel molecular, epigenetic and immunological targets for melanoma therapy, including drivers of tumor invasion and metastasis.

### **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 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. Multiple applications will be accepted from a single institution, provided that each application has a different PI and represents a distinct hypothesis. **An investigator may serve as PI on only one proposal submitted to the MRA under any mechanism in this cycle (this includes collaborating PIs on Team Science Award proposals, and PI's submitting proposals for Special Opportunity Awards)**. 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.

## TYPES OF AWARDS

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

### **MRA Young Investigator Award**

Investigators within 4 years of their first academic faculty appointment will be provided \$75,000/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 insure 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 the project start date 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 Academic-Industrial Partnership Awards (Individual Established Investigator and Team Science Awards)**

These awards are designed to facilitate 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(s) must be academic investigators. Industry scientists may serve as co-investigators or collaborators, but may not be PIs. For Individual awards, PIs with an established record of scientific productivity will receive up to \$100,000/year for 2-3 years from MRA. For TSAs, teams of academic investigators will receive up to \$250,000/year for 2-3 years from MRA. Industry funds (direct costs only) or in-kind support (e.g., reagents, clinical grade drugs, equipment, and contract services) must match but may exceed MRA funds. Therefore, total award amounts may be \$200,000/yr or more for Individual awards, or \$500,000/yr or more for TSAs, for a 2-3 year term. TSA Partnership applications should follow all the guidelines specified for MRA TSAs.

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.

### **MRA Team Science Awards**

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 transforming 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. New for the 2013 award cycle is the requirement that **each team must include at least one Young Investigator as a co-investigator** (see and comply with all Young Investigator eligibility criteria above), who will receive up to \$75,000/year. The Research Plan may include one Pilot Study embedded as an aim or sub-aim, which

articulates a clear hypothesis and translational goals but is not supported by extensive preliminary data. Suggested duration and scope of Pilot Studies is \$50,000/year for 1-2 years.

## **SPECIAL OPPORTUNITY AWARDS**

**MRA-Pfizer Established Investigator Partnership Award:** Applications are solicited to evaluate the therapeutic potential of CDK4/6 inhibition in melanoma. Proposals evaluating biomarkers of response to CDK4/6 inhibition, interactions with dysregulated signaling pathways such as MAPK, combinatorial treatment regimens, and efficacy in treating or preventing resistance to agents targeting signaling pathways or immunologically relevant molecules, are encouraged. A letter of support from Pfizer is required at the time of application. All “letters of intent” for planned research proposals should be sent to Pfizer at its web portal located at [www.pfizer.com/iir](http://www.pfizer.com/iir) with “MRA” clearly stated in the title. Any questions should be sent by email to [IIR@pfizer.com](mailto:IIR@pfizer.com). All email questions should clearly indicate MRA-Pfizer Established Investigator Partnership Award in the email subject line. Please refer to information on Academic-Industrial Partnership Awards for individual established investigators, provided elsewhere in this RFP, for other application requirements and grant terms and conditions.

**MRA-Prostate Cancer Foundation (PCF) Team Science Partnership Award:** Applications are solicited by the Melanoma Research Alliance (MRA) and the Prostate Cancer Foundation (PCF) for one jointly sponsored Team Science Award that will simultaneously advance clinical science in both diseases. A total award amount of up to \$1.5 million over 2-3 years is offered to support innovative, meritorious and translational work with the potential for high clinical impact in prostate cancer and melanoma. The following are examples of investigative areas relevant to both kinds of cancer, for which applications will be considered: 1) nuclear imaging technologies and/or applications as early predictors of treatment outcomes, including novel tracers to distinguish immune from tumor cells in the context of immunotherapy; 2) therapeutic interventions targeting tumor cell metabolism and protein translation; and 3) development of effective combinatorial therapies in the adjuvant or advanced disease setting, based on immune-modulating drugs paired with other agents.

Review of submitted applications will be conducted jointly by PCF and MRA. Please submit one-page letters of intent through proposalCENTRAL, following all of the guidelines specified for MRA Team Science Awards; letters are due by October 15th. Meritorious letters will be selected for submission of full length proposals. Only one application will be selected for funding. Proposals must meet all Team Science Award criteria as specified above.

## **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.

## APPLICATION FORMAT AND DUE DATES

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.

### Team Science Awards

**Letters of Intent are due on October 15, 2012 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. **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 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 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.**

Full length applications will be invited from meritorious LOIs. They must be prepared according to the guidelines given below for full proposals and according to instructions in proposalCENTRAL, and will be due on **January 11, 2013**.

### Young Investigator Awards and Academic-Industrial Partnership Awards

**Complete applications are due on November 15, 2012 at 5:00 p.m. Eastern Time.** Proposals submitted after the deadline will not be considered. In contrast to the Team Science application requirements described above, letters of intent to MRA are not part of this application process.

**Complete 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, and Young Investigators participating in Team Science Award applications, must designate a Mentor and include Mentor letter in 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. Academic-Industrial Partnership Award proposals should contain the complete budget for the project, which includes both the MRA and partner contributions (note 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 and the MRA-Pfizer Established Investigator Partnership Award: 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).

## 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 2008-2012 are provided on our website, <http://www.curemelanoma.org>.

## AWARD ADMINISTRATION

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.

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. Failure to secure such approvals within a reasonable time frame may result in termination of the award.

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.

**Full term funding will be contingent upon review of annual progress reports and other oversight activities conducted by MRA.** Applicants should propose time-dependent milestones by which to measure research progress. Examples of key milestones may include subject recruitment to clinical trials, or the development of necessary research tools and reagents to conduct the project. 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 may be asked to present research findings made under their awards at these meetings.

### **SUMMARY OF TIMELINE AND DUE DATES**

Note that MRA may adjust this timeline without notice to applicants

- October 15, 2012: Team Science Award Letters of Intent due
- November 15, 2012: Young Investigator Award, Academic-Industrial Partnership Award and MRA-Pfizer Established Investigator Partnership Award full length proposals due
- January 11, 2013: Invited full length proposals for Team Science Awards due
- Late February/Early March 2013: Peer and organizational review
- Late March 2013: Awardees notified
- May 1, 2013: Projects start

## 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.

### 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.
- Q: How can I apply for the MRA-Pfizer Established Investigator Partnership Award?
- A: You should first submit a letter of intent to Pfizer requesting support for your concept, at the web portal [www.pfizer.com/iir](http://www.pfizer.com/iir). A letter of support from Pfizer will be required in order for you to submit an application to MRA on proposalCENTRAL.

### Application components

- Q: Is the MRA offering funding for Individual Established Investigator awards during this cycle?
- A: No. Young investigators, team science, and academic-industrial partnership awards are the focus of this grant cycle. The Individual Established Investigator mechanism may be considered in future offerings.
- 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: For Key Personnel, I notice there is no "Co-PI" role available? Why not?



- A: MRA Young Investigator and individual Academic-Industrial Partnership Awards are single PI awards. For Team Science Awards, all PIs are designated as such. Therefore, please do not enter “Co-PI” as a designation for any of the key persons.
- Q: Does MRA require the NIH salary cap to be used when calculating salary and fringe benefits requests?
- 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:

- *August 1 – October 1, 2012*, to Kathy Russell at [krussell@curemelanoma.org](mailto:krussell@curemelanoma.org).
- *After October 1, 2012*, 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).