

## Melanoma Research Alliance 2010 – 2011 Request for Proposals

Melanoma is a leading cause of new cancer diagnoses, and more effective options for prevention, diagnosis and treatment are urgently needed. From a basic and clinical research perspective, melanoma occupies the crossroads of molecular biology and immunology. Melanomas arising in the skin offer a unique opportunity to query lesions at the earliest stages of carcinogenesis for molecular events or signatures predicting progression, invasion and dissemination. As one of the most highly immunogenic human tumors, melanoma provides an ideal context for understanding interactions between the human immune system and cancer. Emerging knowledge about the basic immunology and molecular biology of melanoma has recently begun to translate into significant clinical benefits for patients, but much work remains to be done. The Melanoma Research Alliance (MRA) is a public charity formed in November 2007 under the auspices of the Milken Institute, with the generous support of Debra and Leon Black. To date we have funded 50 research projects worldwide. Please visit <http://www.melanomaresearchalliance.org> for further information on MRA, its research agenda in the *State of Melanoma Research: A Call to Action*, and the research projects funded in our first three award cycles.

### **Objective: *Emphasis on Translational Science***

For the 2010-2011 funding cycle, 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 or melanoma patients. Proposals will be accepted in the following categories: (1) individual investigator awards, including young investigator, established investigator and pilot study awards; (2) team science awards emphasizing collaborative, multidisciplinary research approaches; and (3) *academic-industry partnership awards* for established investigators or research teams (*new this year*). Successful proposals will offer the potential for translational developments that could lead to high impact near-term clinical application in areas of melanoma prevention, diagnosis, staging, and treatment. Development and/or use of novel technologies that have the potential to further such advances in areas of emphasis described below will be considered. Proposals for clinical investigations testing well defined and clearly articulated hypotheses are welcome and should be accompanied by a protocol document; 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 \$5 million in new grant funding during the 2010-2011 cycle.

### **MRA welcomes proposals in the following areas:**

- **Prevention:** Areas of interest include environmental, epidemiological and biological factors in melanoma carcinogenesis.
- **Diagnosis and Staging:** Emphasis includes identification of serological tumor markers, association of molecular tumor biomarkers with prognosis, and development of novel clinical methods for melanoma detection and imaging.
- **Treatment:** Projects emphasizing the translation of scientific findings to the treatment of 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, and development of novel biomarkers of response to therapy.

For the 2010-2011 cycle, proposals in the following areas are of particular interest and will receive special consideration:

- **Developing combinatorial treatment strategies for patients with stage III-IV melanoma. Defining interactions between molecularly targeted and immunologically based therapies, including the development of rational drug combinations based on preclinical models, is encouraged.**
- **Exploring resistance mechanisms to immunotherapies or molecularly targeted therapies, and methods to overcome resistance.**
- **Identifying prognostic biomarkers for patients with Stage I – IIIA melanoma, including conventional molecular and protein-based analyses, as well as studies of epigenetic markers, miRNA markers, and microenvironmental factors.**
- **Defining unique molecular and/or immunological characteristics of acral and amelanotic melanomas in order to identify new therapeutic targets in these patients.**

### **Key Criteria**

- **Innovative and transforming research:** Novel approaches with clear capacity to revolutionize prevention, early diagnosis, staging, or treatment for patients with melanoma or for individuals at high risk for melanoma. Transformative ideas with strong scientific rationale 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 applicability 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) should hold a faculty appointment at an academic research institution within or outside the United States (Assistant Professor 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. Fellows or those in other training 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 different hypothesis.

## **Types of Awards**

Individual Investigator Awards: Only one proposal per PI will be accepted per cycle.

- *Young Investigator Award:* Tenure-track investigators within 4 years of their first academic faculty appointment will be provided \$75,000/year for 2 to 3 years to accomplish innovative, early concept scientific projects.
- *Established Investigator Award:* Investigators with an established record of scientific productivity will receive up to \$125,000/year for 2 to 3 years to conduct projects supported by preliminary data.
- *Pilot Award:* Potentially transformative pilot studies from investigators who are past the initial 4 years of their first academic faculty appointment will be considered for an award of \$50,000/year for 2 years. Pilot proposals are not required to contain extensive preliminary data, but must articulate a clear hypothesis and translational goals.

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.

An investigator may serve as a PI on only one Team Science Letter of Intent per cycle. However, involvement of a Team Science Award PI in other team science applications in a supporting role, such as collaborator or co-investigator, is permitted.

Academic-Industry Partnership 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 (or in the case of Team Science Awards, the Administrative PI) must be an academic investigator. Industry scientists may serve as co-investigators or collaborating PIs (Team Science Awards). Industry funds or in-kind support (e.g., reagents, clinical grade drugs, equipment, contract services) must match but may exceed monetary support from MRA. 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. In order 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. MRA will not claim rights to any new intellectual property or royalties emanating from these projects. 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.

- *Established Investigator Partnership Award:* Investigators with an established record of scientific productivity will receive a total from combined MRA and industry funds of up to \$200,000/year for 2 to 3 years to conduct projects supported by preliminary data.
- *Team Science Partnership Award:* Multidisciplinary teams of two or more PIs will receive a total from combined MRA and industry funds of up to \$1.5 million over 2 to 3 years, according to the specifications outlined 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. MRA must be notified and approve of any significant changes in research objectives, key personnel, or budget.

## **Application Format and Due Dates**

**Applicants will utilize the Proposal Central on-line application tool at <http://proposalcentral.altum.com> and the document templates and requirements therein. Please carefully follow the instructions in Proposal Central. All applications must be formatted in Arial 11 point or Times New Roman 12 point font with ½ inch margins.**

**Individual Investigator Awards:** Complete applications are due on **November 15, 2010**. A complete application includes the following components:

- Title Page
- Applicant/PI information
- Organization/institution information
- Key personnel information
- Lay abstract and technical abstract (250 words maximum each) and key words. The lay abstract will become public if the award is selected for funding.
- 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
- Biosketches for PI and key personnel
- Current and pending support
- Mentor letter of support (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 their work and will provide guidance for the project.

- 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).
- Scientific references for data cited (2 page maximum)

**Team Science Awards: Letter of Intent due February 1, 2011**

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

- Title Page
- 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.
- Letter of intent: **One page maximum** that includes a description of the scientific aims, 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 for individual applications, and will be due on **May 2, 2011**.

**Academic-Industry Partnership Awards:** Complete applications are due on **March 15, 2011**, and should include the following components:

- Title Page
- Applicant/PI information
- Academic institution information
- Corporate partner information
- Key personnel information
- Lay abstract and technical abstract (250 words maximum each) and key words. The lay abstract will become public if the award is selected for funding.
- 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
- Biosketches for PI and key personnel
- Current and pending support
- Non-binding letter of intent from the corporate partner to negotiate a contract with the awardee's institution and provide at least 50% support for the project, in funds or in kind, if the award is granted by MRA.
- 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).

- Scientific references for data cited (2 page maximum)

## **Review Mechanism**

All proposals will be reviewed by the Grant Review Committee of the Melanoma Research Alliance, comprised of peers with diverse expertise in translational cancer research. Applications will be scored according to the Key Criteria listed above. An additional component of the review process will include input from lay audience. **MRA will not provide reviewer critiques or evaluations to applicants.** A listing of GRC membership and descriptions of the projects funded in 2007-2010 are provided on our website, <http://www.melanomaresearchalliance.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. MRA requires certification through Proposal Central of compliance with application Human Subjects/Animal Care Assurance as applicable. **Full term funding will be contingent upon review of annual progress reports.**

For multi-institutional projects, the PIs must verify, in advance, that funds can be transferred from the institution of the Administrative PI to the institutions of the collaborating PIs. This requirement can be easily met by attaching a letter stating a commitment to comply with this requirement from the Administrative PI's business or sponsored programs office.

## **MRA Scientific Retreat**

PIs and, in the case of Partnership Awards, corporate sponsors will be invited to attend the annual MRA Scientific Retreat. PIs will be asked at least once during the award period to present research findings made under their awards.

## **Frequently Asked Questions**

### *Deadlines and dates*

Q: When are the proposals due?

A: The Individual Investigator proposals are due on November 15, 2010. Letters of Intent for Team Science submissions are due on February 1, 2011. Full Team Science proposals, if invited, are due on May 2, 2011. Academic-Industry Partnership proposals, including Established Investigator and full-length Team Science proposals are due on March 15, 2011.

Q: What will be the start date for the award if selected?

A: The earliest start date could be May 1, 2011 for individual awards and August 1, 2011 for team and academic-industry partnership awards. But note that the true start dates may vary.

### *Eligibility*

Q: Must PIs have a tenure-track, academic faculty appointment? Is this a hard-and-fast rule?

A: It is preferred, but evidence of independent investigator status and an environment conducive and supportive of translational research is required.

Q: I am a Fellow at an academic institution. Am I eligible to apply for the Young Investigator Award?

A: No. Only those with a faculty appointment will be considered.

### *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.

Q: Do I need to submit a LOI for the Team Science Academic-Industry Partnership Awards?

A: No. For these awards, only a full proposal is required.

### *Application components*

Q: How are proposals submitted? Do I need to send a hard copy?

A: All proposals must be submitted via Proposal Central, <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 individual awards are single PI awards. Team Science Awards are multiple PI awards. This means that every PI on the team is designated as a “PI” in the Key Personnel list. Therefore, do not enter “Co-PI” as a designation for any of the key persons. Please be clear about who is a PI in the Key Personnel section of the application. The Applicant PI is the Administrative PI.

Q: May I serve as a PI on more than one Team Science Award?

A: An investigator may be designated as PI on only one Team Science LOI per cycle. You may be listed in a supporting role, such as collaborator or co-investigator, on other Team applications.

Q: What needs to be included in the “current and pending support” section?

A: Please submit a listing of all 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 amount of 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.

Q: Is the NIH biosketch format acceptable for submission to MRA?

A: Yes, you may use your NIH biosketch or the template provided in PC.

Q: For Team Science Award full proposal, what needs to be included in the Inter-institutional Team Funding Letter?

A: This is applicable to Team Science Award proposals with PIs from different institutions. Please provide a letter from the business or research office of the Administrative PI's institution that acknowledges that the institution will negotiate and administer subawards to distribute MRA funds to collaborating institutions.

Additional Information: Email questions to [applications@melanomaresearchalliance.org](mailto:applications@melanomaresearchalliance.org)