Melanoma Research Alliance

MELANOMA RESEARCH ALLIANCE - HIDARY FOUNDATION TEAM SCIENCE AWARD FOR ACRAL MELANOMA GENOMICS

Call for Proposals

OVERVIEW

Acral melanoma, which occurs on the palms of the hands, soles of the feet and under the nails, accounts for a small number of melanoma cases but has a survival rate of 10-20% lower than for cutaneous melanomas overall. Recognition that acral melanomas have a distinct genetic profile may account for the difference in survival. Yet, aside from the identification of cKIT alterations in 15-20% of acral melanomas, little is known about other molecular drivers of the disease.

The Melanoma Research Alliance (MRA) is proud to partner with the Hidary Foundation to offer a Team Science Award to **comprehensively characterize acral melanoma patient samples** via state-of-the-art genomic technologies and other analytical approaches in the context of cutting edge biology for new points of therapeutic intervention. Multidisciplinary teams of two or more Principal Investigators (PIs) will receive up to $750,000 USD total over 2 years. There will be only one Award made under this mechanism.

MRA plans to announce its Request for Proposals (RFP) for other funding opportunities in late August. Investigators will be permitted to apply to this and the MRA August RFP as long as the projects are distinct and non-overlapping. **This call for proposals is the primary mechanism for MRA to fund acral genomics in the 2013-2014 cycle**.

Responses to this RFP should include at least the following specific areas of focus:

- Analysis of patient-derived acral melanoma samples (not cell lines)
- Maximizing the comprehensive genomic analysis of those samples
- Integration of such analysis with clinical information from patients providing samples

Applicants should carefully follow the instructions below. Due to the rapid review timeframe for this call for proposals, late or incomplete applications will NOT be considered. Applicants and/or their institutional representatives may contact MRA with any questions they might have prior to the proposal due date. Contact information for the MRA is provided at the end of this document.

KEY CRITERIA

- **Scientific merit:** Outstanding and rigorous proposals as determined by peer review.
- **Capability for rapid implementation and completion and potential for clinical translation:** Proposals that articulate a) a rapid, yet thorough, path to conclusion within 2 years; and, b) a plan to translate findings to the clinic in a rapid timeframe will be strongly favored.

- **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 and have an established record of scientific productivity. 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. Individuals employed by federal government agencies may participate in research proposals as non-funded collaborators, but may not apply for direct funding. An investigator may be a key researcher (PI, co-investigator, or other key role) on two proposals; however, an investigator may only serve as a PI on one proposal in response to this Call for Proposals. PIs share authority for scientific leadership.

APPLICATION PROCESS

Applications are due **Wednesday, July 31, 2013 at 5:00 p.m. Eastern Time.** Late applications will NOT be considered. Applications must be submitted as a single PDF file by email to Laura Brockway-Lunardi, Ph.D., MRA Scientific Program Director at lbl@curemelanoma.org. No hard copies are necessary.

All applications must be formatted in Arial 11 point or Times New Roman 12 point font with no less than ½ inch margins. A single PDF file should be created.

Full proposals must include the following components. Applicants should take care to include the required information. **Incomplete applications will NOT be considered.**

1. **Cover Page** that includes:
    a. Project title
    b. Total budget and duration requested
    c. Applicant PI information: Name, title, address, phone number, and email address of the PI who will be responsible for administrative leadership
    d. Institution information: Name, title, and contact information of a signing official at the Applicant PI's institution
    e. Key personnel information: Identify other PI(s) and key personnel on the team. Proposals must include at least one PI in addition to the Applicant PI.
    f. Signatures: The Applicant PI and the Applicant PI's institutional representative should sign the cover page.

2. **Abstracts (one page to include both):**
    a. **Technical abstract:** Include the number of samples and summarize the technical approaches and key dates.
    b. **Lay abstract:** Include a brief abstract written for a non-technical audience. This abstract will be made publicly available if the project is selected for funding.

3. **Budget detail and justification:** Provide a budget and justification for the project using the template provided by MRA (available on MRA's website and upon request to lbl@curemelanoma.org). Note that MRA will not support indirect costs, overhead costs, or other institutional levies. Fringe benefits for personnel salaries are allowable. Applications demonstrating matching institutional support for MRA funds will receive special consideration.

4. **Curriculum vitae** for PIs and other key personnel: Applicants may use the template provided by MRA (available upon request to lbl@curemelanoma.org) or the NIH biosketch format.

5. **Current and pending research support** for the PIs: Any overlap of current or pending support must be described and explained.

6. **Inter-institutional team letter** (for proposals involving more than one institution): Letter from the Applicant PI's institutional representative confirming that if an Award is granted, the Institution will administer the necessary sub-awards and distribute funds to the collaborating institutions within 30 days of award acceptance by the Administrative PI's institution.

7. **Milestones and timeline** (one page maximum) to include:
    a. Subcontract to participating centers and material transfer agreements (if applicable): Are material transfer agreements already in place to provide for rapid startup? If not, what is the timeline for obtaining them to support rapid conclusion of the sequencing? How will these be expedited?
    b. Approvals, including IRB and patient consent: Please describe the status of IRB approval relevant to the study. Who will be responsible for any needed evaluation of patient consent to confirm sample usability?
    c. Timeline to include obtaining materials, isolating nucleic acid and submission to the sequencing and analytical queues.
    d. Data analysis: How will data be stored, shared and analyzed? What is the timeline for data delivery and analysis throughout the project?

8. **Research Project Description:** 5 pages maximum, inclusive of the following:
    a. Background and list of specific aims
    b. Description of the team, to include: The team that will generate initial results as well as review the results for accuracy, completeness and scientific discovery. Competitive teams will include, for example, melanoma (particularly acral) experts and sequencing and bioinformatics analysis experts.
    c. Preliminary data
    d. Experimental design and methods, to include:
        i. Optimally, multiple technologies will be applied to the same patient sample in the context of informative clinical information and with the potential to complement additional characterization of those samples that either pre-exists or at a subsequent time. How many individual patient samples will be analyzed in this proposal with each approach? Describe the approach to this and any attendant sample strengths or limitations. Will individual patient germline nucleic acid be analyzed?
        ii. Will samples be stratified or pre-qualified? For example, will samples that have certain mutations be included or excluded? Will samples be stratified based on

stage of tumor, outcome data, etc.? Will analysis be focused on primary or metastatic disease?

iii. Specify what technologies will be used (e.g. exome, RNA-seq, whole genome, DNA methylation) and with what intent and how these will expand the knowledge of acral melanoma (e.g. identify mutations in exome or entire genome, measure structural rearrangements, measure expression levels).

iv. Please provide detail that clarifies the sequencing depth and read length relative to the specific technology and question to be addressed, for example, tumor versus normal, exome versus whole genome, etc.

v. Describe the capabilities of the sequencing and bioinformatics facilities, e.g. the number of instruments available and any limitations on accessing the sequencing or data analysis queues.

vi. Given the constraints of the research and technologies proposed above, how many samples are available with sufficient material to support this and possible future projects? Please account for overage needed for technical or analytical failures in this application. Please describe whether these samples arise from one or several institutions and discuss any needed approvals, material transfer agreements, etc.?

vii. Describe any variations in collection, preservation or nucleic acid isolation and discuss potential for technical variability arising therefrom.

viii. Where will the data be stored? How will it be shared in the short and long-term? Are additional costs associated with these functions anticipated?

e. Rationale and fit with key criteria (described above)

9. **Literature references:** Two-page maximum (not included in the five-page research project description).

10. **Support letters**: From each institution represented related to sample collection, processing, sequencing, data analysis, and scientific scrutiny in the context of acral melanoma.

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. 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.

REVIEW MECHANISM

All proposals will undergo rigorous peer review by members of the MRA Grant Review Committee (GRC) and scientific experts appointed by the Hidary Foundation. Applications will be scored according to the Key Criteria listed above and adherence to Project Description requirements (described above). All Awards are contingent upon ratification by the Boards of Directors of the MRA and the Hidary Foundation.

AWARD ADMINISTRATION

Upon acceptance of the award, the Applicant PI and his/her employing Institution will be required to sign an Award Letter within 15 business days indicating acceptance of the MRA's award Terms and Conditions (copy available in advance upon request).

MRA requires certification 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.

Full term funding will be contingent upon review of progress reports and other oversight activities conducted by MRA. Grantees will be required to submit progress reports every six months to the MRA to include progress along the time-dependent milestones included in the proposal. Multi-year support is not automatic for any MRA award and is conditioned on meeting milestones and deliverables, including submission of complete and accurate progress reports. MRA must be notified in advance and approve of any significant changes in research objectives, key personnel, or budget.

MRA SCIENTIFIC RETREAT

PIs will be invited to attend the annual MRA Scientific Retreat and may be asked to present research findings made under their awards at these meetings.

TIMELINE

- June 10, 2013: Call for Proposals released
- July 31, 2013: Full proposals due
- Mid-September: Applicants notified of award
- Executed Award Letter due within 15 days of Award Letter receipt by Institution
- Projects start within 15 days of Award Letter execution

QUESTIONS AND CONTACT INFORMATION

Laura Brockway-Lunardi, Ph.D., MRA Scientific Program Director, lbl@curemelanoma.org or 202-336-8937