Melanoma Research Alliance

RISING TIDE. Foundation for Clinical Cancer Research

2022-2023 REQUEST FOR PROPOSALS

SPECIAL OPPORTUNITY:
RTFCCR-MRA TEAM SCIENCE AWARDS ON PATIENT-CENTRIC MELANOMA CLINICAL TRIALS
July 12, 2022

The Melanoma Research Alliance (MRA) is pleased to announce a Special Opportunity Request for Proposals (RFP) for Team Science Awards focused on patient-centric clinical trials, jointly funded by The Rising Tide Foundation for Clinical Cancer Research (RTFCCR) and MRA. MRA and RTFCCR intend to support two awards through this partnership.

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Rachel Fischer, PhD, at rfischer@curemelanoma.org. For questions on the patient engagement plan or questions for RTFCCR, please email Valerie Behan, PhD at Valerie.Behan@risingtide.ch.

WEBINAR OPPORTUNITY:

If you are interested in learning more about the details of this opportunity and how to engage patients, please register for one of the following informational webinars by clicking the links below. If you are unable to attend, they will be recorded and posted on MRA's website. You can also email Valerie Behan at Valerie.Behan@risingtide.ch with questions pertaining to patient engagement.

- **Tuesday, July 26, 2022 from 9:00 – 10:00 AM ET; register via this link**
- **Thursday, July 28, 2022 from 11:00 AM – 12:00PM ET; register via this link**

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INTRODUCTION

About Melanoma: According to the National Cancer Institute, melanoma is the fifth most common cancer in the United States. 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 remains a substantial need for developing new treatment approaches, including treatment for rare melanoma subtypes, 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 founded in 2007 by Debra and Leon Black, under the auspices of the Milken Institute, with 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 $143 million to support 415 research projects in 19 countries. Please visit www.curemelanoma.org for further information on MRA and the research initiatives funded in prior award cycles.

About RTFCCR: Rising Tide Group is an organization with a strong philanthropic mission. It is based in Schaffhausen Switzerland, however truly global in its reach and activities. Our philanthropic work is organized in two entities – the Rising Tide Foundation (RTF) and the Rising Tide Foundation for Clinical Cancer Research (RTFCCR). Both are charitable, non-profit organizations established in 2010. The Rising Tide GmbH is the service company for both foundations and responsible for the promotion and the offering of philanthropic services of the foundations, for the financial prosperity and operative well-being of the organizations, and for the sustainable income generation. Our philanthropic mission is very close to the heart of our Chairman, who was not only personally impacted by his mother and grandmother's demise to cancer, but is also deeply rooted in an empowerment philosophy. The Foundation was created with the belief that those who are most vulnerable to critical issues and who are willing and ready to take on responsibility are the most effective agents of change and should contribute as members of society with a spirit of freedom to solve their own problems. For more information about Rising Tide, please visit https://www.risingtide-foundation.org/.

SPECIAL OPPORTUNITY:
RTFCCR-MRA TEAM SCIENCE AWARDS ON PATIENT-CENTRIC MELANOMA CLINICAL TRIALS

Letters of Intent due 11:59 p.m. Eastern Time, October 5, 2022
Estimated LOI decisions: November 18, 2022
<u>Invited</u> Full Proposals due 11:59 p.m. Eastern Time, January 18, 2023

The MRA and RTFCCR will jointly support two team awards for clinical trials with the potential to provide significant impact to melanoma patients. These awards seek to support novel, interventional clinical trials with the goal of making a significant difference to melanoma patients in the short term. **Patient engagement must be actively demonstrated throughout the full life cycle of the clinical trial, including planning and dissemination.** For more information, about how to effectively engage patients in guiding research, please watch this [video](#). Specific guidance for preparing a Patient-centric Research Plan can be found [here](#).

We define patient engagement as meaningful engagement of patients in the development of therapeutic, detection, or prevention approaches to cancer care. It encompasses the active and collaborative interaction between patients and researchers across all stages of the research process from conception to results distribution, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

These awards will support innovative approaches with preliminary data, where funding is required to bring better treatment options forward for evaluation in a clinical trial. We welcome applications from all research groups with a track record in melanoma. Grant applicants should actively involve patients in the protocol design.

Term: Up to five years

Amount: Up to $1,500,000. Co-funding is welcome. If the total cost of the trial exceeds $1,500,000, applicants must include a plan to secure the remainder of the funding to ensure the trial can be completed.

Number of Expected Awards: Up to two awards will be supported.

Applicants should submit to the ***RTFCCR-MRA Team Science Award*** LOI opportunity in [Proposal Central.](#)

If selected for funding, awardees will be asked to prepare separate budgets with 50% of support provided by RTFCCR and another 50% from MRA. Each funder's financial support will be governed by its own award agreement terms and conditions with the Administrative PI's institution.

RTFCCR and MRA expect eventual publication of trial results, which should include a description of how and why the clinical trial team engaged patients during the research process and how and it added value to the overall outcome of the study.

OBJECTIVE: *EMPHASIS ON PATIENT-DIRECTED CLINICAL TRIAL*

Purpose:
The purpose of the call for proposals is to solicit high quality research proposals globally to find new approaches to treat melanoma with a focus on early-stage clinical trials, with the goal of making a significant difference to melanoma patients in the short term.

Scope:
At present, there are many early-stage, phase I clinical trials investigating treatment options whereby multiple different treatments for a particular tumor type can yield similar efficacy results. One method to differentiate between available treatment options – and to be more efficient in the development of new treatment options – is to use Health Related Quality of Life or Patient Reported Outcomes to assist with clinical decision-making. While these endpoints are usually captured in randomized phase 3 studies, HRQOL and PROs can be beneficial at all phases of clinical development. During phase 1 clinical trials, the impact of therapeutic agents and combination therapies on toxicity is unknown and traditional endpoints may not fully capture this information. However, this is an area where HRQOL and PRO may add value and can be used to capture symptom quantification or functional improvement or decline. In breast cancer, HRQOL and PROs are used to predict risk for serious adverse events, revolutionizing the way in which clinical trials are implemented. As a result, this collaboration seeks to support early phase clinical trials where patient reported outcomes are used in addition to clinical endpoints to identify and better explore treatment options that best meet the needs of patients with melanoma.

Trial Eligibility Criteria:
Clinical trials are eligible if they meet all of the following criteria:
- Are early-stage and/or first-in-human clinical trials;
- Are an interventional clinical trial or mechanistic study with potential to address unmet patient needs;
- such as improving disease control while reducing side effects and improving quality of life;
- Serve patients interests with primary endpoints that seek to demonstrate clinical benefit;
- Include symptom quantification or functional improvement or decline measurements selected with patient input (HRQOL or PRO);
- Are patient-centric: Applicants must include a patient engagement plan (as defined below) that involves patient partners throughout the clinical trial and planning process;
- Align with the strategic focus areas of RTFCCR and the missions of MRA and RTFCCR;
- Have a high probability to reach patients globally;
- Of special interest are clinical trials or correlative intervention studies focusing on:
    - Repurposing of drugs,
    - Combination therapies,
    - Overcoming therapeutic resistance,
    - Treatment de-escalation, and
    - Next-generation therapies providing better side effect profile than existing drugs;
- Grant activation is expected within three months after the award notification. Therefore, submission of advanced or fully developed protocols are recommended; and
- Basic research, translational studies and research involving animals are NOT eligible to apply.

If applicants wish to apply for immunotherapy or cell-based therapies, they are asked to contact the RTFCCR team to discuss eligibility, by contacting Valerie Behan at Valerie.Behan@risingtide.ch.

Patient Engagement Plan:
The Parties require applicants to submit a "Patient Engagement Plan" as part of the LOI and Full Application. The plan should describe Patient Engagement processes during the generation of the trial application as well as during the trial. It describes engagement e.g., how applicants engaged with the patient community when the research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient engagement model applicants chose for the implementation of the project.

When developing the project budget, adequate and realistic resources for Patient Engagement are required to be reflected in the Patient Engagement Plan and the overall grant budget request. This could include e.g. appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g., travel expenses and meeting venue costs).

Different phases of research will need different patient engagement activities to ensure patient engagement is implemented in the way defined in this document, *for example Phase I, II and III clinical trials require different approaches to patient involvement.*

The parties accept different formats of patient engagement plan, as long as:
- Activities proposed are listed and properly described;
- Activities proposed are designed for patients and with patients; and
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

The Parties define Patient Engagement as meaningful engagement of patients in the development of therapeutic, detection or prevention approaches. It encompasses the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

In this request for applications, the Parties are adopting (Patient-Centered Outcomes Research Institute) PCORI's definition of Patient Partners: it includes patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study. It is important that Patient Partners are not confused with trial participants; Patient Partners are members of the research team and involved in the planning, conducting and dissemination of the research, whereas trial participants are those individuals actually enrolled into the study.

The strategy, modalities, and budgets for Patient Engagement, related deliverables, and expected outcomes must be clearly described in the application.

Guidance for planning Patient Engagement in Research:
Early involvement of Patient Partners, based on co-design principles allows a better formulation of relevant research questions, more credibility of the knowledge produced, identifying, and solving potential challenges faced during the trial, and better application of outcomes to specific contexts.

Below is a checklist to help applicants plan Patient Engagement and complete our Patient Engagement Plan table required to be submitted as part of the Letter of Intent. It encompasses points that should be considered before the trial starts, during the trial and beyond the trial.

Before the trial starts:
✓ Patient Engagement is planned across the entire project lifecycle;
✓ The most appropriate Patient Engagement model is selected;
✓ Appropriate Patient Partners are involved early in formulating the concept and hypothesis; and
✓ Appropriate budget for patient engagement activities and compensation of Patient Partners is reflected in the Patient Engagement Plan and the overall grant budget request.

During the trial:
✓ Assessment of needs of trial participants by Patient Partners is included;
✓ Adaptation of trial and procedures where necessary to meet trial participants' needs; and
✓ Assessment of the impact of patient engagement in the trial at mid-term and at the end of the trial is considered.

Beyond the trial:
✓ Communication and dissemination of study outcomes with patient / public partners is planned after trial's conclusion; and
✓ Collaboration with patient community on trial outcomes is planned.

For more information, please refer to this guide for implementing patient-centric initiatives in health care product development.

Choice of model of Patient Engagement in research projects:
Research teams should think carefully about the activities across the whole project lifecycle that the Patient Partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project. Therefore, depending on the research project, it is important to think about the most applicable role of a Patient Partner for contributing in a clinical trial:

Patient role	Examples	Engagement level
Consultant role	• Patients provide a priori and continuous consultation on outcomes of importance, study design, etc. • Patients are paid investigators or consultants • Patients have a governance role – "a seat at the table"	High
Advisor role	• Patients serve as advisory committee members or provide a priori consultation on outcomes of importance and study design, but have no leadership role or governance authority	Moderate
Reactor role	• Patient input is collected distally through surveys, focus groups or interviews, but patients are not consulted	Low

| | | directly or a priori on such things as study design and outcomes of importance | |
| | | • Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest | |

The Parties require applicants to submit a "Patient Engagement Plan" as part of the LOI and Full Application. The plan should describe Patient Engagement processes during the generation of the trial application as well as during the trial. It describes engagement e.g., how applicants engaged with the patient community when the research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient engagement model applicants chose for the implementation of the project.

When developing the project budget, adequate and realistic resources for Patient Engagement are required to be reflected in the Patient Engagement Plan and the overall grant budget request. This could include e.g., appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g., travel expenses and meeting venue costs).
Different phases of research will need different activities to ensure patient engagement is implemented in the way defined in this document, *for example Phase I first in human studies may require a different approach than a survivorship study.*

The Parties accept different formats of patient engagement plan, as long as:
- Activities proposed are listed and properly described;
- Activities proposed are designed for patients and with patients; and
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

APPLICANT ELIGIBILITY

General eligibility requirements:
- **MRA encourages applications from a diverse pool of investigators with respect to race, gender, sexual orientation, ethnicity, national origin, and disability.** MRA recognizes that diversity in the biomedical research workforce is critical for ensuring that the most creative minds have the opportunity to contribute to realizing our research goals and to ensuring more equitable health outcomes for all.
- **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**.
- PIs must be able to show clear evidence of an independent research program.
- If previously funded by MRA, applicant must be up-to-date on all reporting requirements.
- Fellows or those in other training or research support positions are not eligible to apply.
- Individuals employed by state or federal government agencies may participate in research proposals as non-funded collaborators, but may not apply for MRA funding.
- **An investigator may serve as PI on only one proposal submitted to MRA across any and all of the award mechanisms in this cycle. This includes any Special Opportunity Awards.**

- Mentors for Young Investigator Award applicants may serve as a PI on a separate proposal this cycle; however, that proposal must represent a distinct hypothesis from the Young Investigator's proposal.
- Multiple applications will be accepted from a single institution, provided that each application has a different PI and represents a distinct hypothesis.

RTFCCR-MRA Team Science Award eligibility requirements:
- Team must be multidisciplinary, and consist of two or more established Principal Investigators, one of whom is designated the Administrative PI, a Young Investigator with complementary expertise, and a Mentor for the Young Investigator;
- 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 other Principal Investigators on the team share authority for scientific leadership;
- The Administrative PI and any other Principal Investigators on the team must be senior investigators, past the initial five years of their first academic faculty appointment and must hold a full-time faculty appointment at the level of Assistant Professor (or equivalent) or above. Co-PIs are not allowed. Other investigators on the team need to be designated as Co-Investigators, Collaborators, or Consultants. See Step #6 under the Application Instructions below for additional details and descriptions of these roles;
- An investigator may serve as a PI, including Administrative PI or Principal Investigator on a Team, on only one proposal this cycle;
- **Each team must include at least one Young Investigator and a designated Mentor for the Young Investigator** (the Mentor is not required to have any additional role within the team), 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 provided that application has a unique research focus and hypothesis.

Young Investigator eligibility requirements:
- **<u>Applicants must be within the first five years of their first independent, full time academic faculty appointment at the application deadline, at the level of Assistant Professor (or equivalent position);</u>**
- Applicants must designate at least 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 and provide career mentorship. At least one Mentor with expertise in melanoma research is strongly advised;
- Applicants who have secured an independent full-time faculty position commencing by June 1, 2023 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;
- Applicants do not have to be on a tenure-track; however, fellows or others who are in training positions are not eligible to apply;
- Applicants who are in research support positions are not eligible to apply;

- Applicants who have been awarded a prior MRA Young Investigator Award are not eligible to apply for an additional MRA Young Investigator Award;
- Applicants may serve as PI on only one proposal submitted to MRA for any of the award mechanisms in this cycle;
- **All Young Investigator applicants must complete and return the [Applicant Eligibility Checklist](#) along with the LOI submission.**

If there are any questions about eligibility, please contact Rachel Fischer PhD, MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org before submitting an application. Applications from PIs who do not meet the eligibility criteria will not be reviewed.

REVIEW AND SELECTION CRITERIA

The following criteria will be used to assess the importance, originality, rigor, translational nature of, and degree to which the proposal will lead to rapid clinical benefit.

- **Overall Scientific and Clinical Importance:** Original, innovative, and transformative research approaches with strong scientific rationale and clear capacity to enhance prevention, detection, diagnosis, staging, and/or treatment for patients with melanoma or for individuals at risk will be prioritized. Proposals that articulate a clear path to near-term clinical application will be strongly favored.
- **Rigor and Feasibility:** MRA seeks outstanding and technically rigorous proposals as determined by peer review. Overall study design, methodology, and analyses must be feasible and appropriate to accomplish specific aims.
- **Investigator/Environment:** Applicant has appropriate training, expertise, and evidence of productivity (inclusive of publications, datasets, code, patents, etc.), to carry out proposed research. Applicant's institution and department are sufficiently committed to area of research proposed and to the applicant. Equipment and other institutional resources are sufficient to support the applicant. *In the case of Young Investigator applicants, selected Mentor(s) is appropriate to advance applicant's career and project with evidence of a strong mentorship relationship.*
- Each of the above criteria will account for approximately one-third of the overall score.

LETTER OF INTENT FORMAT AND INSTRUCTIONS

Team Science Award applicants must submit a letter of intent (LOI) to MRA prior to submission of a full proposal (upon invitation). **Please carefully follow the instructions in Proposal Central.**

1. **Title Page:** Enter the project title.
    - Under subprogram, select a Special Opportunity if applicable (otherwise select N/A).

2. **Download 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:** Team Science applications must identify one PI for administrative purposes (the Administrative PI for the proposal). This is the Applicant. The Young Investigator cannot be the Administrative PI.

5. **Organization/Institution:** This is the Administrative PI's institution. If your institution has a [ROR](#) (Research Organization Registry ID), please include.

6. *Key Personnel:* Identify other Principal Investigators on the team as well as the Young Investigator and their Mentor(s). All PIs share authority for project leadership. The position of "co-PI" is not offered under this award mechanism. ORCID IDs are required for PI, Young Investigator and Mentor roles. *Please see Key Personnel requirements and descriptions of roles under step #6 of the Application Instructions section of the RFP.*

7. **Upload Attachments:** Upload the following

   a. **Letter of Intent: <u>One page maximum</u>** 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**.

   b. **Young Investigator Eligibility Checklist:** Required to confirm eligibility. Requires signature of the Department Chair, Division Head, or Dean. Can be accessed [here](#).

   c. **Patient Engagement Plan:** Include a Patient Engagement Plan using the template provided. Specific guidance for preparing a Patient Engagement Plan can be found [here](#).

8. **PI Data Sheet:** Please enter your ORCID ID and other requested demographic information. If you do not have an ORCID ID, you can register for one here: https://orcid.org/register. <u>Please note that requested demographic information will NOT be used by MRA in any way during the selection process. Having such information will help MRA better understand its applicant and awardee pool and detect and address any inequities that exist in the selection process.</u>

9. **Validate:** Check for any missing required information.

10. **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 11:59 p.m. Eastern Time.

Full length applications will be invited from meritorious LOIs by approximately November 18, 2022.

APPLICATION FORMAT AND INSTRUCTIONS (ALL AWARDS)

All applications are due by 11:59 p.m. Eastern Time. Proposals will not be considered after the deadline. Applicants must utilize the Proposal Central online application tool at https://Proposal Central.com/ **and the document templates and requirements therein. Please carefully follow the instructions in Proposal Central and below. Applications include the following steps and components:**

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. Electronic signatures are required to submit the application for submission. ***The Signing Official from the applicant's institution must be provided at least 'Edit' access on this screen to be able to sign.*** Please review the Signature Page to confirm the signature roles required and add as appropriate on this page.
   *PLEASE MAKE SURE TO GRANT ACCESS AHEAD OF TIME TO YOUR INSTITUTION'S SIGNING OFFICIAL TO AVOID ANY LAST-MINUTE ISSUES WITH SIGNING AND SUBMITTING YOUR APPLICATION. *

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. If your institution has a [ROR](#) (Research Organization Registry ID), please include.

6. **Key Personnel:** List and provide contact information for key persons. Include everyone **except the applicant** who will contribute to the scientific development or execution of the project in a substantive, measurable way whether they receive salaries or compensation under the grant. Besides the applicant, ORCID IDs are required for the following roles in Team Science applications: PI, Young Investigator and Mentor.

   Descriptions of Key Personnel roles:
   Administrative PI (required for Team Science applications only): Serves as the team leader and primary point of contact for MRA Staff. Along with sharing scientific leadership with other team PIs, the Administrative PI ensures the team complies with the terms of the award, including all reporting, contractual, and financial obligations. The Administrative PI's institution will oversee all organization assurances and certifications.

   Principal Investigator (PI, required for all applications): This is the applicant for Pilot and Young Investigator applications. For Team Science Award applications, PI(s) share authority for project leadership equally with the Administrative PI. Team Science Award application must include at least one PI, in addition to the Administrative PI.

   Co-Investigator: Co-I's are vital scientific contributors (at the same or a different institution from the Administrative PI), often bringing a needed expertise to the research team. They commit some level of measurable effort to the project and are, therefore, always designated as Key Personnel whether being compensated or otherwise.

Collaborator: Play a lesser role in the thinking and logistics of the project than a Principle Investigator or Co-Investigator. Depending on the role and effort, a collaborator may be designated as Key Personnel (although not required) and may be compensated.

Mentor: All Young Investigator applicants (including Young Investigators on Team Science Awards) must designate at least one mentor who is an established investigator at the same institution as the Mentee. Mentors must ensure that adequate support and guidance are provided for successful completion of the proposed research project and provide career mentorship. **Designating at least one Mentor with expertise in melanoma research is strongly advised.** Mentor(s) must provide a letter of support for the Young Investigator and be designated as Key Personnel.

Young Investigator: Each team must include at least one Young Investigator whose work must be integral to one or more of the aims of the proposal. Young Investigators must be within the first five years of their first independent, full time academic faculty appointment at the application deadline, at the level of Assistant Professor (or equivalent position). Young Investigators must be designated as Key Personnel.

Consultant: Provides guidance on specific aspects of the research project, as their expertise applies. A consultant may be designated as Key Personnel (although not required) and may be compensated.

Others: Key Personnel may also include (but are not required) people at the master's or baccalaureate level (such as Project Managers, Technicians, Postdoctoral Associates, Fellows, Research Assistants or Graduate Students), if they will contribute to the scientific development or execution of the project in a substantive, measurable way whether they receive salaries or compensation under the grant.

REQUIRED SUPPORTING DOCUMENTS FOR KEY PERSONNEL					
Personnel	**Include in KP Section**	**Biosketch**	**Current/Pending Support**	**Letter of Support**	**ORCID ID required**
Administrative PI	Yes (Teams)	Yes	Yes	N/A	Yes
Principal Investigator	Yes (All)	Yes	Yes	N/A	Yes
Co-Investigator	If applicable	Yes	No	Optional	No
Collaborator	If applicable	Yes, if included as KP	No	Optional	No
Mentor	Yes (Young Investigator, Teams)	Yes	No	Yes	Yes
Young Investigator	Yes (Teams)	Yes	Yes	No	Yes
Project Manager	Optional	Yes, if included as KP	No	No	No

Technician	Optional	Yes, if included as KP	No	No	No
Consultant	If applicable	Yes, if included as KP	No	No	No
Postdoctoral/Fellow	Optional	Yes, if included as KP	No	No	No
Graduate Student	Optional	Yes, if included as KP	No	No	No
Other (such as research asst, etc.)	Optional	Yes, if included as KP	No	No	No

7. **Data and Renewable Reagent Sharing Plan:** In order to promote rapid research advancement, transparency, reproducibility, and collaboration, MRA encourages the open sharing of data and resources generated from its funded awards. Provide information for the types of data and renewable reagents that will be generated as part of the award and how they will be shared.

   MRA has adopted the following **Data Sharing Policy**:

   - MRA **recommends** the posting of manuscripts based on or developed under an MRA Award to a pre-print server ahead of or at the time of journal submission.
   - MRA **recommends** the posting of research outputs (data, code, software) to public data repositories at the time such research outputs are generated.
   - MRA **recommends** that manuscripts based on or developed under an MRA Award be published in open-access journals.
   - MRA **recommends** that all research outputs based on or developed under an MRA Award (including publications, data, code, and software) be made available with no commercial modification rights (e.g. CC BY-NC license).
   - MRA **requires** that the final, accepted version of any publication based on or developed under an MRA Award be deposited in PubMed Central so that it is available 12 months after publication.
   - MRA **requires** that any data, code, and/or software needed for the independent verification of published research results based on or developed under an MRA Award be curated and made freely and publicly available at the time of publication.

   MRA will incur costs associated with policy compliance, provided these fees (e.g. article processing charges, data storage), are included in the original grant application budget.

8. **Abstracts and Keywords:** Provide a general audience abstract (non-technical) and a technical abstract (2,000 characters, *including spaces,* maximum each) and keywords. Please note: the general audience abstract will become public if the award is selected for funding, therefore, it should not contain any proprietary information.

9. **Budget Period Detail:** Enter budget detail for each award period requested. The funds must be used for research-related costs.
   Permissible Direct Costs include the following:
   - Personnel expenses including salary, wage, or stipend with fringe benefits. Supplies and materials requests should be itemized by category.
   - Equipment purchase requests are allowable and applicant must demonstrate that the equipment is directly used and vital for the conduct of the project. Equipment requests may be denied upon further review of the full application and will be funded only upon approval from Rising Tide and MRA.
   - Other direct cost requests can include patient care costs and contract services.
   - Travel costs are allowable by MRA and upon approval by RTFCCR.
   - Please also include any costs associated with compliance to MRA's data sharing policy.

   Indirect Costs: This RFP will not support indirect costs, overhead costs or other institutional levies. However, fringe benefits for personnel salaries are allowable.

10. **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 Proposal Central forms (2,000 characters), applicants may upload the budget justification in document form in step #13.

11. **Current and Pending Research Support:** Please list all current and pending support for the Applicant. For Team Science applications, please also list all current and pending support for any appropriate Key Personnel (Principal Investigators and Young Investigators ONLY). For Young Investigator and Pilot applications, current and pending support is only required for the Applicant.

    Any overlap of current or pending support with the MRA proposal must be described and explained. Current and pending support can be added to your (and other Key Personnel's) Professional Profile on Proposal Central by clicking on the 'Professional Profile' tab and going to Step #6: Other Support.

    To add your entries, please click on the "+" link and all entries previously saved in your Professional Profile will show. Please select the applicable support, and save. For Key Personnel (Administrative PI, Principal Investigators, and Young Investigators ONLY), if they have granted you at least 'View' access to their profile, you can select Other Support from their profile as well. If they have not provided you 'View' access, please download the "Current and Pending Support" template provided in step #2 of the application, fill it out with their Other Support, and upload the completed document as an attachment in step #13.

12. **Organizational Assurances:** IRB and IACUC approvals, if applicable.

13. **Upload Attachments:** Upload the following:
    a. **Biosketch for PI and Key Personnel**: Please upload an NIH format biosketch for yourself and all Key Personnel listed in step #6. Biosketches for research support staff, students, postdocs and other training positions are not required. Applicants who do not have an NIH biosketch may use the template provided in Proposal Central. Besides publications, MRA welcomes the inclusion of research outputs such as datasets, code, patents, and papers posted to preprint servers.

b. **Current and pending research support:** Use this template <u>ONLY</u> for Key Personnel where the applicant does not have access via Proposal Central to their support. Whenever possible, please enter PI and Key Personnel support directly into Proposal Central in the "Current and Pending Support" section (step #11). Use the template provided in Proposal Central (in steps #2 and #13) to provide information on all current and pending support for appropriate Key Personnel (Administrative PI, Principal Investigators, and Young Investigators ONLY) not included in step #11. <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, statistical plan, figures (which may be embedded within the above sections), and rationale/fit with key criteria, including the potential for clinical impact.

d. **Literature references:** A list of up to 30 references supporting the project description is allowed, in addition to the 5-page project description.

e. **Mentor Letter of Support**: Include letters of support from any Mentor(s) designated in the Key Personnel section of the application. The letter(s) 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: https://tinyurl.com/yapwnw3a

f. **Young Investigator Applicant Eligibility Checklist**: Required to confirm eligibility. Requires signature of the Department Chair, Division Head, or Dean. Must be returned via email to Rachel Fischer Ph.D., MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org by October 5, 2022 (LOI deadline). Please also upload a copy as part of the application. Can be accessed here.

g. **Patient Engagement Plan:** Include a Patient Engagement Plan using the template provided. Specific guidance for preparing a Patient Engagement Plan can be found here. Incorporate any feedback provided by MRA staff (will be emailed separately to the applicant).

h. **For proposals involving clinical trials:** Attach a brief protocol synopsis (5 pages maximum), along with a timeline and milestones, including but not limited to IRB and regulatory approval (if applicable), patient accrual timeline, and timeline for completion of analyses.

i. **Application checklist:** Please fill out to ensure all application materials are complete and applicant is eligible to apply.

14. **Statement of Proposal's Fit Within MRA's Research Program**: Provide a brief statement (up to 2000 characters) of how the proposed research project fits within MRA's overall research portfolio, which can be found here: https://www.curemelanoma.org/grants/. If the work builds on a previously funded project(s), please explain.

15. **PI Data Sheet**: Please enter your ORCID ID and other requested demographic information. If you do not have an ORCID ID, you can register for one here: https://orcid.org/register. Please note that requested demographic information will NOT be used by MRA in any way during the selection process. Having such information will help MRA better understand its applicant and awardee pool and detect and address any inequities identified.

16. **Validate**: Check for any missing required information.

17. **Signature Page(s)**: *Before submitting the application*, an electronic signature is **required** from both the Applicant/PI and a Signing Official from the applicant's institution. Type your name in the text box and click the green 'Sign' button. A date and time stamp will appear next to the button indicating that the electronic signature was successful. To give the Signing Official access to sign this application, enter their information in Step #3: "Enable other users to access this proposal" and grant them at least "Edit" access.

18. **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 11:59 p.m. Eastern Time or on weekends.

TIMELINE

All application deadlines conclude at 11:59 p.m. Eastern Time. Proposals submitted after the deadline will not be considered.

- **October 5, 2022:** Deadline for Letters of Intent (LOI) for Team Science Awards
- **November 18, 2022 (estimate):** Meritorious LOIs for Team Science Patient-Directed Clinical Trial Awards invited to submit full proposals
- **January 18, 2023:** Applications are due for Team Science Patient-Directed Clinical Trial Award full proposals
- **May 2023:** Awardees notified (Note that MRA may adjust the notification date without notice to applicants)
- **June 1, 2023:** Projects start

REVIEW MECHANISM

All proposals will undergo rigorous peer review by a joint Scientific Review Committee appointed by the MRA and RTFCCR. (Full listing of the MRA GRC is available here: www.curemelanoma.org/GRC). Applications will be scored according to the Review and Selection Criteria outlined above. To minimize any real or perceived conflicts of interest (COI), MRA asks reviewers to adhere to a rigorous set of COI guidelines. MRA also provides reviewers with curated resources to help mitigate any potential implicit bias in the review process. Further information about these guidelines and resources are available upon request. Please contact Rachel Fischer Ph.D., MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org. All awards are contingent upon ratification by both the MRA's and RTFCCR's Board of Directors. **MRA will make every effort to provide brief, written reviewer feedback on full applications to all applicants; however, occasionally such comments may not be available due to**

unforeseen circumstances. A listing of all research projects funded by MRA, along with abstracts, are provided on our website, and are searchable by investigator, institution, or award at www.CureMelanoma.org/grants.

AWARD ADMINISTRATION

AWARD LETTER
Upon acceptance of the award, the Administrative PI and their employing Institution will be required to sign an Award Letter indicating acceptance of the MRA's Award Terms and Conditions within 30 days. Rising Tide will contract with the awarded Administrative PI's Institution for their portion of the award funds using Rising Tide's Grant Contract. If you would like to request a copy of MRA's or RTFCCR's Award Terms and Conditions to review ahead of applying, you may do so by emailing Rachel Fischer PhD, MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org or Valerie Behan PhD, Rising Tide's Senior Scientific Program Manager, at valerie.behan@risingtide.ch MRA must be notified in advance and approve any significant changes in research objectives, key personnel (including transfer to another employee), or budget.

APPROVALS
MRA requires certification through Proposal Central 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. **Awards 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. Under each of its Grant Contracts, Rising Tide will pay the grant recipient against pre-set milestones (more fully described in the Grant Contract) as reflected in a written research progress report prepared by the grant recipient.

MRA SCIENTIFIC RETREAT

PIs 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 out of the agency budget, and as such, travel for the retreat should not be included within your submitted budget. The 2023 Annual Scientific Retreat is scheduled for March 8-10, 2023 in Washington, DC.

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 appointment is not required. Evidence of independent investigator status and an environment conducive and supportive of melanoma 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. **To confirm eligibility, Young Investigator applicants must complete the [Applicant Eligibility Checklist](#)** (see additional FAQs for Young Investigator applicants).

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. PIs 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.

Young Investigators

Q: I do not hold the title of Assistant Professor but I do hold the title of my institution's entry level, full-time faculty position. Am I eligible to apply?

A: Appointments such as research assistant professor, adjunct assistant professor, assistant professor research track, instructor, or lecturer may be eligible to apply as long as your institution considers this an independent, faculty-level position and you have independent lab space. If you are uncertain, please verify your eligibility by the LOI deadline, by emailing Rachel Fischer Ph.D., MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org.

Q: I am within my first five years of an Assistant Professor position, but previously held an entry level full-time faculty position such as research assistant professor, adjunct assistant professor, assistant professor research track, instructor, or lecturer, either at my current institution or at a different institution. Am I still eligible to apply?

A: If you held any independent faculty-level position prior to **November 2, 2017**, then you are not eligible to apply.

Q: I will be past the first five years of my first faculty appointment at the time the project starts. May I apply for a Young Investigator Award?

A: Yes, as long as you are within the first five years of your first faculty appointment <u>at the time of proposal submission</u>.

Q: I will be past the first five 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 five 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 as a Young Investigator?

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) and complete the Applicant Eligibility Checklist.

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. It is strongly advised that Young Investigator applicants have at least one Mentor with expertise in melanoma research.

Q: I would like to have a Mentor that is not at my institution. Is this allowed?

A: No. All Young Investigator 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.

Q: Are Mentors of Young Investigator applicants allowed to be a PI of an existing MRA award or award application this cycle?

A: Yes, however, each research proposal must have a distinct hypothesis and scientific aims.

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.

Q: What is the expected level of percent effort for a Young Investigator?

A: There is no specific requirement around percent effort, but MRA encourages a minimum of 10% effort on the project.

Application components

Q: Do I need to have an ORCID ID?

A: Yes. MRA now requires that all applicants provide an ORCID ID, as well as the following Key Personnel roles: PI, Young Investigator, and Mentor. 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 requests that applicants and selected Key Personnel roles (PI, Young Investigator, and Mentor), provide demographic information in Proposal Central; 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 any inequities that exist in the selection process.

Q: How are proposals submitted? Do I need to send a hard copy?
A: All proposals must be submitted electronically via Proposal Central, https://Proposal Central.com/. Proposal Central will only accept electronic signatures on applications.

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 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 Proposal Central.

Q: Is the NIH biosketch format acceptable for submission to MRA?
A: Yes, MRA encourages you to use your NIH biosketch. You may also use the template provided in Proposal Central.

Q: Who should I reach out to if I have a question about patient involvement in the clinical trial?
A: If you have any questions about patient involvement, please contact Valerie.Behan@risingtide.ch

ADDITIONAL INFORMATION AND CONTACTS

Email questions about this RFP, eligibility, or other issues about MRA or its awards to Rachel Fischer PhD, MRA Senior Scientific Program and Registry Manager, at rfischer@curemelanoma.org. For questions on the patient engagement plan or questions for RTFCCR, please email Valerie Behan PhD, Rising Tide's Senior Scientific Program Manager, at Valerie.Behan@risingtide.ch.

Technical questions about the Proposal Central 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 ET, Monday through Friday.