



Melanoma Research Foundation Request for Proposals (RFP) 2020

RESEARCH OVERVIEW:

The Melanoma Research Foundation (MRF) is committed to advancing research across the spectrum of melanoma – from prevention through diagnosis, staging, treatment and survivorship. The MRF proactively partners with the NCI, Congress, the Department of Defense and other foundations to develop and collaborate on a broad agenda for melanoma research that takes full advantage of all opportunities, while also sharing challenges. Since 1998, the MRF has funded 187 innovative, high impact, basic, translational and clinical research projects. Further, in 2019, the MRF awarded over \$1,500,000 in *new* melanoma research. In 2020, the MRF will again offer Established Investigator and Career Development Awards (as discussed in this RFP), as well as Medical Student Awards and a Young Investigator Team Award to advance the field of translational immuno-oncology (detailed in separate RFPs available on the MRF website).

Please visit www.melanoma.org for additional information on the MRF and to learn more about previously funded research. All questions or concerns regarding the MRF's Research Grant Program can be directed to the Program Director at research@melanoma.org or by calling 800-673-1290.

TYPES OF AWARDS OFFERED IN 2020:

Available through this award mechanism

Established Investigator Awards (EIA)

The EIAs provide funding of **up to \$100,000 per year for two years** to established melanoma researchers, or senior researchers working in closely related fields who wish to move into melanoma research.

Career Development Awards (CDA)

The CDAs provide funding of **up to \$50,000 per year for two years** to junior investigators. Researchers who are beginning a research career focused on melanoma are eligible. This year, the MRF will also offer specific career development awards focused on **Pediatric Melanoma (PED CDA)**.

Available through a separate award mechanism *(please refer to the MRF website for additional details)*

Young Investigator Research Team Award

The MRF, through its Breakthrough Consortium (the MRFBC), is pleased to offer the MRFBC Young Investigator Research Team Award to advance the field of translational immuno-oncology, generously funded by a grant from Bristol-Myers Squibb (BMS). This grant provides funding of **up to \$150,000 per year for two years** to an investigative team consisting of junior investigators and senior mentors.

Medical Student Awards

The Medical Student Awards provide funding of **up to \$3,000 for one year** to medical students at accredited U.S. medical schools or institutions. These awards provide opportunities and

funding for medical students to engage in short clinical or laboratory-based research projects focused on better understanding the biology and treatment of melanoma.

SPECIFIC TOPIC PROPOSALS (STPs):

Scientific topics that address unmet clinical needs in melanoma research were identified through a series of meetings of multidisciplinary experts from the MRF's [Scientific Advisory Committee](#) and [Breakthrough Consortium Steering Committee](#). The following categories are the identified unmet needs in melanoma research selected as STPs for 2020 (details on each of these categories noted on p.8 of this RFP):

- ❖ ***Therapy Resistance (both immune & targeted therapy)***
- ❖ ***Adjuvant and Neoadjuvant Therapy***
- ❖ ***Dormancy and Metastasis***
- ❖ ***Brain Metastases and Leptomeningeal Disease***

Applicants must clearly indicate which of the categories – if any – is being addressed in their application. Applications are not required to address these STPs, although those that do might be given extra consideration. However, in all cases, the scientific merit is the most important factor underlying the selection for funding.

ELIGIBILITY & REQUIREMENTS:

General (for all grant types)

- Applicants must hold a PhD or MD degree or equivalent at the time of the grant submission.
- For this RFP, applicants may be the PI or co-PI on only one submitted application.
- Applicants are eligible to respond to other MRF RFPs, as long as the research proposals are significantly different.
- American citizenship is not required. However, for all grants, the proposed research must be conducted in a non-profit research organization, a medical institution or an educational institution located in the United States.
- Applicants must show evidence of strong departmental or institutional support and commitment.
- PIs and co-PIs may not have an active research award with the MRF (please note: awards currently under no-cost extensions are not considered as active research awards).
- The use of relevant genetic models and/or human derived tumor samples is highly encouraged, but not required.
- Applicants may, but are not required to, submit applications focused on one of the STP unmet needs.
- Proposed research must comply with all applicable National Institutes of Health (NIH) animal and human welfare guidelines.
- Applicants are encouraged to discuss any eligibility questions with the MRF prior to applying.

Established Investigator Awards (EIAs)

- Applicants must have a title equivalent to Associate Professor or higher at the time of the grant submission. Both tenured and non-tenured track faculty are encouraged to apply.

Career Development Awards, including the Pediatric Melanoma CDA (PED CDA)

- Applicants who are postdoctoral fellows must have less than 5 years of postdoctoral experience at the time the grant will be awarded and must not have previously received any major grant support (e.g. from ACS, NIH, NCI, or DoD).
- Applicants who are not postdoctoral fellows may have a title of Research Associate/Scientist, Staff Scientist, Instructor, Assistant Professor, or equivalent at the time of the grant submission. For individuals in this category, previous grant support (e.g. K08, K99, K22, etc.) is allowed.
- For the Pediatric Melanoma CDA (PED CDA), the proposed research must focus on pediatric melanoma.
- Applicants are required to have at least one mentor; their biosketch must be included in the application. Please note: mentors do not have to be at the applicant's own institution.

REVIEW PROCESS:

The MRF's Research Grant Program emphasizes basic, translational and clinical research projects that explore innovative approaches to understanding critical problems pertaining to prevention, diagnosis, staging and treatment of melanoma. All proposals will undergo rigorous peer review, where reviewers are selected based on their expertise in diverse areas of basic, translational and clinical melanoma research. Reviewers include members of the MRF's Scientific Advisory Committee (SAC) and the Breakthrough Consortium (MRFBC) as well as members of the scientific and clinical melanoma community who are not in conflict with the application. Proposals receiving discrepant scores are subjected to interim review by a panel selected from the initial review group. Applications with the highest scores (including those that received a high score in the interim review) are then assessed by a panel of representatives from the initial review group. The top ranked grants are recommended for funding to the MRF Board of Directors. The number of grants selected for funding is determined by the MRF Board of Directors, based on available funds.

AWARD ADMINISTRATION AND REPORTING:

Award decisions will be made on or around **August 2020**. Upon acceptance of the award, the PI and the Institution will be required to sign an award letter accepting the MRF's terms and conditions.

Awards will cover research conducted over a two-year period. Funds are distributed four times each year, on or around December 31, March 31, June 30, and September 30 for a total of eight payments over two years. A no-cost extension may be permitted with sufficient justification from the PI and approval from the Program Director. Requests for a no-cost extension must be made within 30 days of the award period expiration.

Interim financial and scientific progress reports are to be submitted to the MRF no later than 30 days prior to the end of the grant's first year. Final financial and scientific reports, detailing all activities during the award period, are to be submitted to the MRF within 60 days of the end of the award period (even if a no-cost extension is requested).

Acknowledgment of support from the MRF must accompany any published report using data or findings from research conducted under an award from the MRF. The intellectual property reviewed remains solely within the institution.

STEP-BY-STEP APPLICATION INSTRUCTIONS:

The MRF will accept applications from January 6 - March 2, 2020 for the 2020 award cycle. The deadline is March 2, 2020 at 5 pm EST. All submissions, notifications and critiques will be completed entirely online through ProposalCENTRAL (<https://proposalcentral.altum.com/>).

Please read the instructions carefully prior to beginning the online grant submission process.

NOTE: Applications that represent resubmission of previously proposed studies, in whole or in part, may be submitted for consideration only twice; however, there is no restriction on the timing of the resubmissions. A one-page letter referencing the project title, a summary of changes to the application from the previous submission, and responses to reviewers' criticisms must be uploaded as an attachment during Step 11: Upload Attachments.

Step 1: Title Page

The project title should not exceed the space provided (75 characters, including spaces).

Choose the grant program to which you are applying (and if applicable, please select the STP category in which you are applying):

- Established Investigator Award (EIA) – up to \$200,000 over a two year period
- Career Development Awards (CDA) – up to \$100,000 over a two year period – this includes the CDA focused on pediatric melanoma (PED CDA)

The research period for all awards is a two-year period beginning October 1, 2020 and ending September 30, 2022.

Please specify if this is a new application or a resubmission.

Step 2: Enable Other Users to Access This Proposal

You have the option to allow other individuals access to your application. You can choose from three different levels of permission.

Step 3: Applicant/PI

Profile information is pre-loaded in this section. You may update your profile information here as well.

Step 4: Institution and Contacts

Institution information and contact information can be updated and/or changed here.

Step 5: Key Personnel

Key personnel, other than the applicant, who will provide support to the project, will be listed here. If this is a Career Development Award (CDA or PED CDA) application, the PI should also list their

mentor in this section. The Biosketch of the mentor and/or key personnel will be required in Step 11: Upload Attachments.

Step 6: Environment

Please provide a description of your institutional environment in which the research will be conducted. Please describe how this environment will contribute to the probability of success (e.g. institutional support, physical resources including laboratory, office space, and common use facilities contributing to the proposed work, etc.). For all CDA applications, including the PED CDA, please also provide an overview of the institutional investment in the success of the investigator (e.g. travel, training, collegial support including the availability of organized peer groups, logistical support such as administrative management/ oversight, and financial support such as protected time for research with salary support) as well as a description of your career goals/ objectives including any career development/ training activities that will occur during the grant period.

Step 7: Abstracts

Scientific Abstract

In the space provided, include a summary of the proposal that gives a brief description of the objectives, rationale, methods and expected results. The total length of the summary may not exceed 3,000 characters (including spaces) and should be written in scientific terms.

Lay Abstract

In the space provided, include a brief (<3,000 characters, including spaces) summary of the proposal. The lay level abstract needs to be written so that the everyday person can understand the significance, impact and innovation of the proposed research.

Keywords

Please select up to six appropriate keywords (from the list provided) that characterize the proposed research project.

If the project is awarded, portions of the abstracts may be used in the MRF's various publications, press releases, fundraisers and educational events.

Step 8: Budget Period Detail

Awards will be made for a two-year period. Please fill out the budget information for **both years**.
Please note for all grants:

- **Only direct costs are allowed.**
 - **Cost of living adjustments for personnel or non-personnel costs are not allowed.**
 - **When calculating salaries, please use actual costs – not the salary allowed by the NIH salary cap.**
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- **Established Investigator Awards (EIA)**

Personnel Costs

All personnel may be named in this section. The salary and fringe benefits included in the budget is calculated based on total of salary and fringe benefits multiplied by the % effort. The MRF will consider up to 15% of the salary of the EIA recipient and/or any co-PIs; and up to 100% of the salary for a postdoctoral fellow, graduate student, and/ or technician.

Non-Personnel Costs

All budgeted expenses such as consumable supplies, animal costs, service fees and consultant fees must be itemized. Requests for major equipment will be closely scrutinized, should be carefully justified, and should not exceed 15% of the total (two year) budget. Indirect institutional costs are not allowed. Allowable travel expenses for meetings and research purposes – including to international meetings – are capped at \$2,000 per project year.

Established Investigator Awards will not exceed \$100,000 per year.

- **Career Development Awards (CDA), including those for pediatric melanoma (PED CDA)**

Personnel Costs

All personnel may be named in this section. The salary and fringe benefits included in the budget is calculated based on total of salary and fringe benefits multiplied by the % effort. The MRF will consider covering up to 50% of the salary for a CDA recipient. Mentors should not be salaried. Salaries for senior investigators, postdoctoral fellows, graduate students, and/or technicians can be included if they will contribute to the proposed aims and data to be obtained.

Non-Personnel Costs

All budgeted expenses such as consumable supplies, animal costs, service fees and consultant fees must be itemized. Requests for major equipment will be closely scrutinized, should be carefully justified, and should not exceed 15% of the total (two year) budget. Indirect institutional costs are not allowed. Allowable travel expenses for meetings and research purposes – including to international meetings – are capped at \$2,000 per project year.

Career Development Awards will not exceed \$50,000 per year.

Step 9: Budget Summary

This is a summary of the Budget Period Detail. Also, please give a brief justification for each budget item here.

Step 10: Organization Assurances

Information regarding human subjects, vertebrate animals, and/or recombinant DNA will be entered here (if relevant). If an application has just been submitted, please note that as well.

Step 11: Upload Attachments

All attachments must be in PDF form. Uploaded documents should fall under one of the following descriptions:

Biosketch – A NIH biosketch must be uploaded for all listed personnel in Step 5 as well as the applicant. Career Development Award (CDA, PED CDA, and BM CDA) applicants must also include a NIH biosketch for their mentor. Biosketches must list in chronological order, previous employment, personal statement, positions and honors, contribution to science and research support/scholastic performance.

NIH Other Support Pages – The NIH Other Support Pages (both active and pending) must be uploaded for all listed personnel in Step 5 as well as the applicant. This must include information

about all types of available research support (including direct costs and percent effort). Career Development Award (CDA) applicants, including those applying for the Pediatric Melanoma (PED CDA), must also include this information for their mentor. Briefly describe any possible overlap of the active/pending support with the proposed project. Please note: for CDA applicants, there should be no funding overlap between the CDA applicant's proposed project and the mentor's funded research.

Letter of Support – A letter of support from your institution is required (for Team Awards, only a letter of support for the PI is required); additional letters of support are allowed. This letter should be from the department chair or other leader at the institution with direct knowledge of the applicant's value to the department and institution. A research laboratory head may write a letter of support for a postdoctoral fellow CDA applicant; however, for all other CDA, as well as EIA and Team applicants, it is anticipated that the letter of support will come from a departmental chair or other institutional leader. The letter should also mention the trajectory of the candidate in terms of leadership within the department or institution.

Other – If the application is a resubmission of a previously proposed study, a summary of changes to the application from the previous submission, and responses to reviewers' criticisms must be uploaded here. This file must be limited to 1 page in length.

Research Plan – The research plan is limited to **6 pages, Arial font, at least 11pt font with ½ inch margins.** Single line spacing is acceptable. The text of the Research Plan should contain sufficient information for the evaluation by the reviewer panel and should cover:

1. Specific Aims (if the application addresses one or more STP, please cite the topic)
2. Background, rationale, and significance. Include a statement of significance of the proposed work, its clinical relevance to melanoma prevention, diagnosis and/or treatment, potential for further research and the potential for securing future funding for the project.
3. Preliminary Data: results of previous research related to the Project Title. Specify how the original research objectives have been met and include justification of support based on exceptional findings. If the original research objectives were not met or were modified, an explanation must be included.
4. Experimental design and procedures
5. References (References ARE NOT counted in the 6 page limit)

Signature Page – The signature page should be printed out, signed, scanned, and saved to your computer to be uploaded here.

Step 12: Validate

Click the 'Validate' button here to check for any missing required information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the next step.

Step 13: Signature Page(s)

You may print the signature page(s) after you have completed all the proposal sections.

Step 14: Submit

Submit your application. You will be unable to submit if you have not provided all the required information. We encourage you to submit your application as early as possible so that we can assist you with any issues that may arise. **The deadline is March 2, 2020 at 5 pm EST.**

SPECIFIC TOPIC PROPOSALS (STP) AREAS:

A. *Therapy Resistance (both immune and targeted therapy)*

Although long term-responses have been seen to both targeted therapy and immunotherapy, many patients still show signs of resistance. Key questions include: what are the molecular determinants of poor responses to BRAF-MEK inhibitor therapy, can effective predictive markers of immunotherapy response be developed, can we overcome immune exhaustion and how can immunologically “cold” tumors be made “hot”?

B. *Adjuvant and Neoadjuvant Therapy*

1 in 4 patients who undergo surgical resection for early stage melanoma will relapse. Adjuvant therapy is frequently given to minimize recurrence, but it is often highly toxic. Improved prognostication methods and biomarkers are urgently needed to identify the patients who are both at high risk for recurrence and have disease that would be responsive to a particular type of adjuvant therapy. Also, the neoadjuvant platform is providing exciting early information about efficacy for single agents and combinations. A key question is: how to best use the neoadjuvant approach to optimally develop combination regimens and identify early blood and imaging biomarkers that are associated with long term benefit?

C. *Dormancy and Metastasis*

A subset of patients with early stage melanoma relapse many years after “curative” surgery, suggesting that melanoma cells may remain dormant for long periods of time. Little is known about the nature of dormancy, the mechanisms underlying dormancy, or why these melanoma cells eventually escape dormancy and become clinically relevant. Moreover, melanoma metastases remain the major cause of patient morbidity and mortality. New insights are urgently needed into the metastatic cascade, as this may offer new areas for therapeutic intervention.

D. *Brain Metastases and Leptomeningeal Disease*

Very little is understood about the biology of melanoma brain metastases or leptomeningeal disease. Although responses have been seen to immunotherapy and targeted therapy in patients with brain metastases, limitations exist. For example, response durations are shorter in the brain than systemically for targeted therapies and many patients with symptomatic disease are unable to be treated with immunotherapy. Therefore, a key question is: how do we produce durable responses in patients with symptomatic CNS metastases including melanoma leptomeningeal metastases?

FREQUENTLY ASKED QUESTIONS:

How do I apply for a grant?

The grant application will be available ONLY during the time applications are being accepted. During that time, you can apply for a research grant online at <http://proposalcentral.altum.com/>.

What is the deadline?

Applications will be accepted from January 6 - March 2, 2020 at 5pm EST.

Do I need to be a U.S. citizen?

No. However, the proposed research must be conducted in a non-profit research organization, a medical institution or an educational institution located **in** the United States. Prior to submission, the interested PI should inquire for eligibility and obtain specific approval from the Program Director.

Am I eligible?

Please read all eligibility requirements. Should you have questions not answered here, please contact the Program Director at research@melanoma.org.

How many grant programs are currently funded by the foundation?

In 2020, the MRF will fund a total of 4 different grant programs: the MRFBC Young Investigator Team (up to \$300,000 over a two-year period), Established Investigator (up to \$200,000 over a two-year period), Career Development – including a CDA for pediatric melanoma (up to \$100,000 over a two-year period), and Medical Student Awards (up to \$3,000 over a one-year period).

What is the difference between the programs?

The MRFBC Young Investigator Team Award is for junior investigators and mentors working as a team on immunotherapy research. The Established Investigator Awards are designed for senior researchers. The Career Development Awards (including the PED CDA) are designed for junior researchers. The [Medical Student Program](#) is designed for current medical students.

How long is the research plan section of the grant?

The research plan is limited to 6 pages, not including references.

What information is included in the project plan?

The text of the research plan should contain sufficient information for evaluation by the review panel. The plan should cover specific aims, background, rationale, significance, results of previous research directly related to the project title, experimental design and procedures and references. Please note: If the application is in response to a STP, the background section could be streamlined as the reviewers already realize the relevance/significance of the research.

Can an award be transferred to a new institution?

A grant can be transferred upon approval of the Program Director. The MRF envisions that for postdoctoral fellow CDA Awardees, whom may be transitioning to independent faculty positions, this may be a common occurrence. For detailed criteria and instructions, please contact the Program Director at research@melanoma.org.

Term	Definition
Key Personnel	The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition.
Principal Investigator (PI)	This is the grantee responsible for all activity being supported by the grant. He or she is responsible and accountable to the MRF for the proper conduct of the project or activity. Also known as Program Director or Project Director.
Other Support	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, start-up funds, prizes or gifts.
Institutional Animal Care & Use Committee (IACUC)	Established at institutions in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals with broad responsibilities to oversee and evaluate the institutions' animal programs, procedures, and facilities. IACUC review and approval is required for all PHS supported activities involving live vertebrate animals prior to funding.
Institutional Review Board (IRB)	IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.
Clinical Trial	<p>A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases:</p> <ul style="list-style-type: none"> • Phase I: Testing in a small group of people (e.g. 20-80) to determine and evaluate safety (e.g. determines a safe dosage range and identify side effects). • Phase II: Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety. • Phase III: Study to determine efficacy in large groups of people (from several hundred to several thousands) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use. • Phase IV: Study done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.