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CAREER DEVELOPMENT GRANT AWARD GUIDELINES

The Marfan Foundation, Loeys-Dietz Syndrome Foundation and The VEDS Movement are requesting proposals for the Career Development Grant Award. Proposals are now being accepted for two-year \$100,000 (\$50,000 per year) grants in basic, translational, or clinical research. This grant program is designed to support investigators early in their career to derive preliminary data in a key concept area that has high potential to lead to extended funding from NIH, EU, and other large research funding sources.

SCHEDULE

Application Deadline: October 26, 2022

Announcement of Awards: March 1, 2023

Funding Available: July 1, 2023

SPECIAL AREAS OF INTEREST

Special areas of interest are basic research, translational studies and clinical studies in cardiovascular, orthopedic, pulmonary, pain, ophthalmologic and other pertinent disciplines. Studies can consider novel animal model systems, new DNA/RNA technologies, artificial intelligence (AI) innovation, and any synergistic collaborations that may provide identification of new interventional targets and possible new therapies for Marfan syndrome, VEDS, EDS, LDS, and other genetically triggered aortic and vascular conditions.

CONTACT

Please direct all questions and correspondence to:

Lauren May, MPH
Research Director
The Marfan Foundation
22 Manhasset Avenue
Port Washington, NY 11050
Email: lmay@marfan.org





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PROCEDURE FOR SUBMISSION, REVIEW, AND AWARD OF CAREER DEVELOPMENT GRANTS

A. INTRODUCTION

The Marfan Foundation and its divisions award grants to support research related to Marfan syndrome, VEDS, EDS, LDS, and other genetically triggered aortic and vascular conditions. One goal of the Foundation's Research Program is to advance research in this area and to identify methods for earlier diagnosis, improved therapies, and to find an eventual cure. A second goal is to support investigators early in their career to develop preliminary data in a key concept area that has high potential to lead to extended funding from NIH, EU, and other large research funding sources.

B. TYPES OF PROPOSALS SOLICITED

Each application should have the quality of an NIH proposal. Special areas of interest are basic, translational and clinical studies in cardiovascular, orthopedic, pulmonary, pain, ophthalmologic and other pertinent areas utilizing synergistic collaborations; novel theories; novel animal model systems; AI innovation; DNA/RNA technologies for identification of new targets and new therapeutic therapies. The award is designed to support investigators studying any discipline. Special consideration is given to proposals in non-cardiac disciplines and clinical research areas.

C. BUDGET

Applicants may request up to \$50,000 per year for two years.

D. QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR (PI)

The principal investigator must hold an MD, DO, PhD, ScD, DDS, DVM, or equivalent degree. The investigator must have proven ability to pursue independent research as evidenced by original research publications in peer-reviewed journals. Applicants must have less than seven years of experience in a faculty position at the time of application submission and have never received an NIH R01 grant award or similar grant award. If the applicant has already received an R01 grant, the applicant must apply to the Foundation's Innovator Grant Award Program, even if they do not hold an Associate Professor position. Appointments associated with clinical house staff/fellowship training positions will be excluded from the seven-year limit. Applicants cannot hold an NIH K grant, or other training grant simultaneously with The Marfan Foundation Career Development grant. Applicants cannot receive more than one Career Development Grant from the Marfan Foundation during the seven-year experience limit. Work can be performed in the U.S. or internationally, and non-U.S. appointments are acceptable.





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E. REVIEW PROCESS

The Foundation's Scientific Advisory Board, a committee of experts in basic, translational, and clinical research, will review each application. The NIH peer review study section model will be followed. Each proposal will receive a priority score based on the evaluation of the committee. Priority scores will be forwarded to The Marfan Foundation where award decisions will be made based upon relative scientific merit ranking of the submitted grants, and on priorities of The Marfan Foundation. All applications will be held in the strictest confidence, and all decisions by The Marfan Foundation are final.

F. TERMS OF THE AWARD

1. Duration

Two-year funding period begins July 1, 2023 and ends June 30, 2025.

2. Changes of Status of Principal Investigator

If the named PI changes affiliations, the award will follow only after approval of transfer from The Marfan Foundation. If the named PI ceases research in the field for which the award was made, the award will terminate and the remaining balance will be returned to The Marfan Foundation.

3. Site of Project

Awards are for studies at international or national universities, public or private universities, colleges, hospitals, and biomedical research institutions. The PI will make all arrangements for the execution of the proposed research projects.

4. Budget

Budgets for up to, but not exceeding, \$100,000 for two-years are acceptable (i.e., \$50,000 per year). Payments will be made to the PI's institution which will be responsible for administering the funds. Salaries for PIs, support personnel, or current research post-doctoral fellows engaged in the project may be requested. Any unexpended funds shall be returned to The Marfan Foundation upon completion of the granting period unless extension is approved by The Marfan Foundation. The Marfan Foundation does not pay for institutional overhead, construction or renovation; purchase of major capital equipment; office equipment or furniture; travel (except as required to perform the project); tuition fees; journal subscriptions, dues or memberships; equipment service contracts; or salaries for secretaries. Funds will be distributed semi-annually.

5. Indemnification of The Marfan Foundation

Principal Investigator, co-investigators and his/her Affiliated Institution will be obligated to indemnify The Marfan Foundation from any and all liability that may arise from the PI's/Affiliated Institution's conduct and The Marfan Foundation affiliation therewith due to the grant relationship.





6. Institutional Support

The PI assumes responsibility for conducting research projects and supervising the work of co-investigators. The PI must demonstrate that access to a suitable caseload or patient population will be available for study during the funding period for clinical studies.

7. Use of Animals and Humans in Biomedical Research

All PIs must certify that the research facilities, its researchers, and employees adhere to the Animal Welfare Act, National Research Council Guide for the Care and Use of Laboratory Animals, and any appropriate U.S. Department of Agriculture or National Institutes of Health Regulations and Standards or similar country standards. An Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) or its equivalent must approve research involving human subjects or animals, and a copy of the approval or pending approval must be sent with this application. Copies of annual IRB renewals must be forwarded to The Marfan Foundation. IRB/IACUC approval must be documented prior to dispensation of The Marfan Foundation's funds. The application must include letters of support if the proposed project uses facilities not routinely available to or directly under the supervision of the sponsoring program.

8. Publications

All discoveries resulting from work supported in part by The Marfan Foundation should be made available to the public and scientific community through approved scientific channels such as national meetings and peer reviewed publications. Publications will acknowledge the support of The Marfan Foundation. A PDF copy of the publication must be forwarded to The Marfan Foundation.

9. Publicity

The Marfan Foundation shall be permitted to use the PI's name, image and likeness, as well as the name of the Affiliated Institution, in connection with all statements, printed materials, or electronic media related to the Grant Award or related to The Marfan Foundation's Research Program. At the Foundation's request, the PI will provide The Marfan Foundation with appropriate photographs and biographical information to be used in connection with this grant.

10. Intellectual Property (IP)

Pursuant to the Foundation's established policy, inclusion of the IP provisions is a condition for the Foundation making a grant and entering into all research agreements. See Exhibit I.

11. Progress and Financial Reports

The PI must provide a progress report and a financial report no later than 45 days after the completion of the first 10-month period and at the completion of the grant. Failure to provide such reports will preclude the PI from obtaining further funding. Consideration for future funding will be dependent upon completion of these progress reports. An additional and final questionnaire will be forwarded to the grant recipient





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after the completion of the grant to describe any publications and subsequent funding received based on research performed using the Foundation's funds.

G. CONTACT INFORMATION FOR CORRESPONDENCE

Lauren May, MPH
Research Director
The Marfan Foundation
22 Manhasset Avenue
Port Washington, NY 11050
Email: lmay@marfan.org

H. DETAILS OF PROPOSAL

The application must be submitted electronically, including the application forms, additional pages, and appendices, as a single PDF file, via The Marfan Foundation website, marfan.org.

Please name your application using the following format:

CareerDevelopment_LastName_FirstName.pdf

The application forms may be completed using the free Adobe Reader program. If you do not already have it, you can download it at <http://www.adobe.com/products/reader.html>. The Title Page form requires dated signatures; you may either insert a digital signature and date or print the form and then scan it to include in your application PDF.

Pages should be numbered at the bottom. Minimum font size for text is 12 point. Appendices should not be used to subvert the page limitation on the grant; however, figures, tables, diagrams and photographs can be placed in the appendices. Please present the proposal in the order that follows.

- 1. Title Page: 1 page**
 - a. Application form provided
- 2. Table of Contents: 1 page**
 - a. Application form provided
- 3. Project Abstract and Lay Person Summary: 1 page each**
 - a. On a single page, describe precisely and clearly the nature, objective, methods of procedure, and significance of the proposed research project, and how it relates to the goal of providing a better understanding of Marfan syndrome, VEDS, EDS, LDS, and other related conditions and/or improving the treatment or diagnosis of Marfan syndrome, VEDS, EDS, LDS, and other related conditions (limit 300 words).
 - b. Rewrite the abstract in terms suitable for presentation to lay persons (limit 500 words).





- 4. Research Plan: 3 pages**
 - a. Include Goals and Objectives; Rationale; Methodology; Evaluation. (Figures should be placed in appendix).
- 5. Please comment upon the importance of funding:**
 - a. Will this funding allow you to pursue studies that would otherwise not be performed? Is funding meant to supplement other sources of support?
 - b. Do you anticipate that this funding will increase your competitiveness for other funding sources?
- 6. Please comment upon the significance of the work that you propose:**
 - a. Is it similar to or a direct extension of work that has been or is being performed elsewhere?
 - b. Does the work complement or extend other studies that are being performed at your institution?
 - c. How novel are the studies that you describe?
 - d. Would such a proposal be competitive for NIH funding in its current form, or would you require additional preliminary data?
 - e. Do you anticipate that the support would lead to the generation of physical resources that might be useful to other investigators in the field?
 - f. If so, would you be willing to make them widely available?
- 7. Budget and Justification**
 - a. List full budget with amount requested. Include:
 - i. Names, titles, time/percentage effort of all participants, requested salaries, and fringe benefits.
 - ii. Supplies needed to complete project.
 - iii. A statement that the institution or other funding sources will absorb indirect costs.
 - iv. A written budget justification. The budget justification should be suited to the proposal. It is important that the investigators match the dollar award with the actual project. If funding from other sources is being used to cover certain parts of the study, please elaborate on what parts of the budget will not be completed with Foundation funding and what the approximate costs of the full project would be. No overhead or indirect costs will be considered. List the additional sources of funding if budget exceeds proposal amount.
- 8. Other Support: 2 pages:**
 - a. List other support received by principal and co-investigators for any projects (include yearly and total budget and duration of any grants):
 - i. Current
 - ii. Pending
 - iii. Description (in a paragraph, describe each current or pending grant and whether it has scientific or budgetary overlap with the present proposal).
- 9. Biographical Sketches: 5 pages each**
 - a. Using the supplied form, please provide biographical sketches for key personnel. Indicate the total number of publications in each of the (2) categories: referenced articles and invited works. If you prefer, you may use the NIH biosketch form instead.





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10. Facilities Description: 1 page

- a. Describe the research facilities (laboratory space, clinical population, etc.) available for the project.

11. Appendix

- a. Figures, tables, etc.
- b. Literature cited
- c. Human subjects experimental approval
- d. Vertebrate animal experimental approval

I. EXHIBIT I to Research Grant Recipient Agreement

Patent, Intellectual Property and Technology Licensing Policy of The Marfan Foundation (this “Policy”)

Effective Date: March 15, 2021

Although one of the primary purposes of The Marfan Foundation (the “**Foundation**”) in funding scientifically meritorious research is to advance its mission, the Foundation recognizes that inventions having public health, scientific, business or commercial application or value may be made in the course of research supported by the Foundation. It is the desire of the Foundation that such inventions be administered in a manner that they are brought into public use at the earliest possible time. The Foundation recognizes that this may be best accomplished through patenting, copyrighting, and/or licensing of such inventions.

Certain capitalized terms used in this Policy that are not otherwise defined herein shall have the meanings set forth below:

“**Invention**” is any discovery, composition of matter, method, process, product, program, software or know-how, whether or not patented or patentable or copyrighted or copyrightable, that is conceived or reduced to practice in the performance of a Foundation award and has an application of value such that its use, licensing, lease or sale can generate revenue.

“**Award**” is the Foundation funding mechanism and accompanying financial support given to a specific institution to support the work and/or training of a specific Investigator and any Co-Investigators (as defined below).

“**Institution**” is the entity (university, medical center, hospital, research institute or any other organization) in which the work and/or training supported by the Foundation funding will be conducted.

“**Principal Investigator**” (and/or “**Co-Investigator(s)**” if applicable) is the individual(s) receiving the award and responsible for the conduct of the research supported by a Foundation Award.

“**Collaborating Investigator**” is an individual who contributes in a substantive way to the scientific development or execution of the project.





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“Inventor(s)” is the Investigator, Co-Investigator(s) and/or Collaborating Investigator(s) (if applicable) who made an Invention.

Inventions are subject to the Foundation’s Patent, Intellectual Property, and Technology Licensing Policy as set forth below:

1. All Inventions shall be reported in writing to the Foundation within sixty (60) days of the date when the Invention is disclosed to the Institution where the work was done, and prior to any public disclosure. The report to the Foundation should be the initial copy of the Institution’s Invention disclosure form and any subsequent versions that have substantive changes or additional information.
2. If the Institution receiving or disbursing the Foundation funds that support the Invention has an established and applicable patent, intellectual property or technology transfer policy and procedure for administering Inventions, the Foundation will defer to that policy with the following exceptions and requirements which shall control in the event of a conflict:
 - a. Title to any Invention shall reside in the Institution; and title may be permitted to reside in the Inventor(s) or any other person or institution with the prior written approval of the Foundation, upon advice of the Foundation’s legal counsel and science advisors, except that no Foundation approval is required for title to reside in the United States Government.
 - b. Institution and Investigator(s), if appropriate, shall promptly determine whether they desire to seek patent or other statutory protection for an Invention and shall notify the Foundation in writing within sixty (60) days of the decision to seek (or not seek) such protection. The Foundation also will be notified in writing within sixty (60) days of a patent application being filed, and any patent subsequently being issued, and/or of a license, lease, sale or revenue generating agreement concerning the Invention prior to their execution. No patent or patent application shall be abandoned without prior notification by the Institution or Inventor(s) to the Foundation and offering to assign to Foundation all right, title and interest to the Invention to the extent permitted by law.
 - c. Notwithstanding any other provision of this Policy, the Foundation shall participate in the income derived from the Invention. The Foundation’s participation shall be determined, within one year or a reasonable period of time after reporting of the Invention to the Foundation, by mutual agreement between the Institution or other titleholder and the Foundation, with the Foundation’s rights hereunder not being affected if such determination is not made within said time period. The amount of the Foundation’s participation shall be guided by the principle that the Foundation’s sharing of income shall be in proportion to the Foundation’s portion of support for the work or research giving rise to the Invention. The Foundation waives receipt of income until the cumulative net





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income (i.e., net of any direct out-of-pocket patenting costs) from an Invention conceived or reduced to practice from the performance of a Foundation Award exceeds \$500,000.

- d. The Institution or other titleholder, when it licenses an Invention to another party for commercialization, shall include provisions in the license obligating the licensee to commercialize the Invention in a diligent manner and meet appropriate diligence requirements and concrete development milestones to avoid the license terminating, and the Institution or other titleholder shall monitor performance of the licensee relative to these requirements and milestones. The Institution or other titleholder, or its designee or licensee shall take commercially reasonable steps to bring the invention to practical or commercial application in a reasonable time period (based on type of Invention) after issuance of a patent or other clear determination of commercial value. If the Institution or other titleholder, or its designee or licensee, has not taken commercially reasonable steps and cannot show reasonable cause why it should retain title to and all rights in the administration of the Invention for a further period of time, then, if no other parties have superior legal rights, the Institution or other titleholder and the Foundation shall determine a course of action including but not limited to
 - i. the Institution or other titleholder's renegotiation of milestones with the current licensee or termination of the current license and licensing of the Invention to another licensee;
 - ii. a non-exclusive right to the Institution or other titleholder to practice the Invention for any non-commercial purpose;
 - iii. a global, exclusive or non-exclusive, non-revertible, royalty-free license to the Foundation;
 - iv. the provision to the Foundation of any additional materials necessary for regulatory filing and the technology's enablement that might be in the possession or control of the Institution or other titleholder, except for intellectual property that was not generated as a result of the Foundation's assistance; or
 - v. any other action appropriate in the circumstances.
4. If the Institution has no established and applicable patent, intellectual property or technology transfer policy or procedure for administering Inventions, title to any invention shall reside in the Institution or Inventor(s) as agreed by them and the Institution and Inventor(s) shall comply with all requirements in Sections 2.b and 2.d and the Foundation shall have all rights set out in Sections 2.c and 2.d.
5. The right of the Foundation to participate in revenue derived from an Invention pursuant to section 2.c is not waived in these situations:
 - a. **Multiple funders.** If any Invention is conceived or reduced to practice from the performance of research funded by the Foundation and by independent funding from





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another health agency or funding organization, not an agency or department of the United States Government, the Inventors and the Institution will work with the Foundation to negotiate with the other agency/organization in good faith for a mutually satisfactory determination of rights to administer the Invention and determination of the fair share of the royalty or other income to be paid to the Institution, Inventor(s), the Foundation and other parties who independently funded such research.

- b. **Federal funders.** Notwithstanding any other provisions of this Policy, if an Invention is conceived or reduced to practice from the performance of research funded by the joint support of the Foundation and an agency or department of the United States Government, the Foundation may defer to the patent, intellectual property or technology transfer policy of the United States Government.

