



2019 YOUNG INVESTIGATOR GRANT

REQUEST FOR PROPOSALS

MDS Foundation, Inc.
4573 South Broad Street
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Yardville, NJ 08620

lharrison@mds-foundation.org

Please visit www.mds-foundation.org/YIG for the most up-to-date information.

MDS FOUNDATION, INC.

Mission: The MDS Foundation, Inc. (MDSF) is an international organization devoted to the support and education of patients and healthcare providers with innovative research in the fields of MDS and related myeloid neoplasms in order to accelerate progress leading to the control and cure of these diseases.

Vision: By building an international community of physicians, researchers, and patients, we will make potentially curative therapies available for all patients with MDS.

For more information, please visit our website at www.mds-foundation.org.

Grant Summary

The purpose of this Young Investigator Grant is to provide an investigator, aged 40 years or less, the opportunity to initiate, continue or complete a project that focuses on either basic or clinical management into the causation, epidemiology, molecular biology, cytogenetics, morphology, prognosis and treatment of the Myelodysplastic Syndromes or related myeloid neoplasms.

Funding may be used towards salary support, technician support, supplies, equipment, travel, etc. necessary for the pursuit of the recipient's research project. The grant period is from July 1, 2019 through June 30, 2020.

Grant Eligibility Requirements

1. An investigator, US or International, that is 40 years old or less on the date of application submission
2. The proposal must be for research into MDS or related myeloid neoplasms

Please note: There is no exception to these requirements.

Payment Schedule from the MDS Foundation, Inc.

All payments will be made to the designation in section 8 on the application. The MDS Foundation, Inc., will mail payments based on the following schedule:

| | |
|------------------|----------|
| July 1, 2019 | \$12,500 |
| January 15, 2020 | \$12,500 |

Physician Payments Sunshine Act

The Physician Payments Sunshine Act, or "Sunshine Act", is part of the Patient Protection and Affordable Care Act (health care reform) that passed in 2010. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and healthcare companies. The Sunshine Act requires manufacturers of pharmaceutical drugs and devices, as well as group purchasing organizations, to report payments or transfers of value made to U.S. physicians and teaching hospitals.

The MDS Foundation understands that payments made through MDS Young Investigator Grants are **not reportable** under the Sunshine Act as indirect payments or transfers of value because these awards are **not funded** by companies that are considered manufacturers of pharmaceutical drugs and devices and/or group purchasing organizations.

Progress Reports from Recipients

Progress reports shall be submitted based on the following reporting schedule. (Sample reports are available on our website at www.mds-foundation.org/YIG.) Future funding is subject to timely submission and satisfactory review of these reports. The final report should summarize the full project. Both reports must include the following components:

1. Institution's Name
2. Primary Investigator's Name and Telephone Number
3. Reporting Period
4. Program summary and Results to Date
5. Signature of Principal Investigator

Reporting Schedule Dates

| | |
|--|------------|
| Mid-term Progress & Expenditure Report | 12/31/2019 |
| Final Cumulative Progress & Expense Report | 08/01/2020 |

Application Process

All applications must be submitted in accordance with the requirements and instructions of this Request for Proposals (RFP). All application materials must be in English and must be submitted online at www.mds-foundation.org/YIG.

Completed applications (including all uploads) must be submitted by **Thursday, February 28, 2019 at 11:59 pm ET. No late applications will be accepted.** Applicants are encouraged to submit early because technical help will *not* be available after 5:00 pm ET on February 28th.

Applications must include the following **mandatory** components:

1. Contact Information (including a copy of passport or driver's license)
2. Project Information (includes Abstract, IRB and Animal Use Assurances)
3. Specific Aims
4. Applicant's Biosketch
5. Research Strategy
6. Cited References
7. Project Timeline
8. Budget and Justification
9. Mentor's Letter of Support

The following are **optional** components:

1. Clinical Protocol
2. Prior Publications (maximum of two publications)
3. Additional letters of support

Important Instructions about Attachments. Attachments can be in PDF, MS Word, or MS Excel formats, although PDF format is preferred, and must be in accordance with document page limits. Documents should not be password protected.

Description of Mandatory Components

- 1. Contact Information.** This section includes the following information about the applicant:
 - Name
 - Date of Birth (copy of passport or driver's license must be uploaded with application)
 - Institution
 - Department
 - Degree(s)
 - Address
 - Phone
 - Email
- 2. Project Information.** This section includes the following information about the proposed project:
 - Project title
 - Subject area
 - Research focus area(s)
 - Assurances for use of human and/or animal subjects in the research proposal
 - Abstract – a brief abstract of the research proposal must be submitted (<100 words)
- 3. Specific Aims.** List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. The specific aims should state concisely and realistically what the research intends to accomplish and/or what hypothesis is to be tested, and should list measurable objectives for the proposed project.

4. Applicant's Biosketch. Applicants may use their current NIH biosketch if they have one available or they may use the biosketch template available on our website at www.mds-foundation.org/YIG. The biosketch must have no more than four (4) pages.

5. Research Strategy. The research strategy should be limited to **four** (4) typewritten, single-spaced pages. ALL pertinent tables, pictures, and graphs **MUST** be included within the **4-page limit**.

The Research Strategy must contain the following information:

- Significance and Background:

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or critical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will change if the proposed aims are achieved.

- Innovation:

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

- Approach:

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work. Please include appropriate detail and/or documentation to assure a reviewer that your project is feasible in the timeframe of the grant.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Clearly state the applicant's role in the project (i.e. writing of protocol, performing the assays, etc.). When human subjects are involved, the precautions to ensure patient safety and confidentiality and the relevance or implications for patient care should be explained.
- List and describe the facilities and resources available to conduct the study, including a description of industry support for any clinical trials.

6. Cited References. A list of cited references in the Research Strategy should be submitted as a separate document along with the application.

7. Project Timeline. Enter major milestones for your project, the expected completion date, and if there is an associated deliverable. A deliverable is something that can be included in a progress report, such as a publication or an approval letter. You are not required to have deliverables. However, the timeline should make it clear what outcomes will be achieved during the grant period.

- 8. Budget and Justification.** The grant funds will be directed to the sponsoring institution and should be used towards salary support, technician support, supplies, equipment, travel, etc. necessary for the pursuit of the recipient's research project. Grant funds may not be applied to patient care costs that are reimbursable by a third-party payor, or to tuition or fees for academic courses. The budget must be completed. Budget justification must be entered for each line item requested.

The budget guidelines are as follows:

- **Total Award:** The total award amount is \$25,000 for one year, payable on July 1, 2019 and January 15, 2020 in two equal installments. The proposed budget must not exceed the total award amount.
 - **Research support:** At least \$21,500 should support costs directly related to the research project such as personnel salary, supplies, equipment, and other expenses. Budgeted items must be consistent with available institutional facilities and resources. Patient care costs that are reimbursable by a third-party payor, and tuition and fees for academic courses are unallowable costs.
 - **Travel:** Up to \$1,000 can be allotted for the applicant's travel to the MDS Foundation's International Symposium on Myelodysplastic Syndromes to attend the Awards Ceremony and for any other travel essential to conducting the study. We would be **very pleased** if you would attend the MDS Foundation's Awards Ceremony which will take place during our International Symposium on Myelodysplastic Syndromes, May 8-11, 2019 in Copenhagen, Denmark – <https://mds.kenes.com/2019>.
 - **Indirect costs:** Up to \$2,500 (or 10% of the total award amount) may be applied to overhead or facilities and administrative costs of the recipient's institution in administering the recipient's research project.
- 9. Mentor's Letter of Support.** Please identify a mentor from your sponsoring institution. The mentor's contact information including name, phone number, and email address must be in the application. The Mentor Letter should include the following information:
- Training plan for the applicant, including intended structure of the mentor/investigator interaction during the proposed investigation
 - A critical review of both the applicant and the research proposal
 - The role of the applicant in the development of the proposal
 - The role(s) or anticipated role(s) the applicant holds (will hold) at the institution
 - The level of institutional commitment to the applicant's career development as an independent clinical investigator
 - Assurance that the applicant's sponsoring institution will provide adequate facilities and support for performance of the proposed work

Description of Optional Components

- 1. Clinical Protocol.** If your project involves a clinical protocol, please submit a copy of the protocol with your application.
- 2. Prior Publications.** Up to two prior publications may be included. The applicant must be a co-author on these publications. Please submit a copy of each publication with the application.
- 3. Additional Letters of Support.** If you would like to include additional letter(s) of support with your application, please attach the additional letter(s) in one single PDF file containing all the additional letters of support.

Important Dates

Applications Open: January 15, 2019
Applications Due: February 28, 2019 by 11:59 pm ET
Notification Date: April 2, 2019
Grant Term: July 1, 2019 - June 30, 2020

*****Completed applications must be submitted before the deadline on Thursday, February 28, 2018 at 11:59 pm ET. No late applications will be accepted.***

Application Changes

Withdrawal of Application. Please advise the MDS Foundation promptly at lharrison@mds-foundation.org should you decide to withdraw your application for any reason. Your email should include your name, the title of your proposal, and the reason for your withdrawal.

Change of Institution or Position. If at any time during the application or review process you have a career plan change or leave your current position, please notify the MDS Foundation.

Mentor Change of Institution. If at any time during the application or review process your mentor leaves his/her current position or institution, please submit this change to the MDS Foundation.

Budget Changes. If any changes to the submitted budget are expected that could result in a deviation of 10% over or 10% under, a budget revision request must be submitted in writing. This revision request should include justification for the changes along with a revised budget.

Research Changes. If any changes are anticipated in the goals or results of the research, a plan should be submitted in writing with a clear explanation of the changes.

Submit all Changes, Reports, Questions to: Lea Harrison at lharrison@mds-foundation.org. All change requests and reports will be reviewed by the MDS Foundation's staff and members of the MDS Foundation's Board of Director's Research Committee.

Award Notification

All communication will be sent to the primary email address entered for the applicant. Please make sure that this email address is correct. Please add lharrison@mds-foundation.org to your safe senders list and/or check your spam folder if you are not receiving communications such as document submission notifications, application submission confirmation, etc. YI Grant applicants can expect to be notified by April 2, 2019 via email to their primary email address.

Young Investigator Grant

CHECKLIST

Mandatory Components

- Contact Information – including copy of passport or driver's license
- Project Information – including Abstract (<100 words), IRB, and Animal Use Assurances
- Specific Aims
- Applicant's Biosketch (4 pages maximum)
- Research Strategy (4 pages maximum including tables, pictures, graphs, single spaced)
- Cited References
- Project Timeline
- Budget and Justification
- Mentor's Letter of Support
- Required Signatures

Optional Components

- Clinical Protocol
- Prior Publications (maximum of two publications)
- Additional Letters of Support

Completed applications must be submitted before the deadline on *Thursday, February 28, 2019 at 11:59 pm ET*. No late applications will be accepted.