



Request for Proposals Hemostasis and Thrombosis Research Society (HTRS) 2020 HTRS Mid-Career Research Award (MCRA) Program

The 2020 HTRS MCRA Program is supported by a medical education grant to HTRS from Genentech.

**Letters of Intent (LOIs) are due Friday, March 20, 2020 by 11:59 PM ET
Full Proposals are due Monday, July 20, 2020 by 11:59 PM ET**

**All application materials must be submitted on the HTRS Online Grant Submission site:
<https://htrs.smapply.org>**

About the Hemostasis and Thrombosis Research Society

Incorporated as a nonprofit organization in 1994, the Hemostasis and Thrombosis Research Society, Inc. (HTRS) is the leading North American professional society dedicated to research, mentoring, workforce development, and continuing medical education for physicians, investigators, and all health care professionals interested in advancing care for people with hemostatic and thrombotic disorders. To learn more about HTRS, visit www.htrs.org.

Goals of the HTRS Mid-Career Research Award Program

The goals of the HTRS Mid-Career Research Award (MCRA) Program are to:

- Advance the science underlying the molecular basis or clinical management of hemostasis or thrombosis by supporting investigator-initiated research to ultimately improve the health and well-being of people living with blood disorders
- Provide financial support to talented mid-career investigators to enable them to transition from mentored research to full research independence
- Combat the shortage of skilled academic researchers in benign hematology by supporting mid-career investigators in the U.S. and Canada at a critical juncture in their research careers. Upon completion of a project funded by the MCRA Program, the recipient (or recipient team) should be ready to apply for a large-scale grant to expand their research such as an R01 or R34 from the National Institutes of Health

(NIH) in the U.S. or the equivalent from another agency such as the Canadian Institutes of Health Research (CIHR)

Applicant Eligibility Requirements

Basic Requirements

The MCRA is not intended to be a bridge mechanism for established investigators, but to help mid-career investigators make the transition to full research independence.

Eligible candidates for the MCRA must fulfill the following requirements:

- Mid-career physician-scientists (MD, MD/PhD or DO) committed to academic research careers in non-malignant hematology (or careers that have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis, such as obstetrics/gynecology, adolescent medicine, neonatology, etc.). “Mid-career physician-scientists” are defined by HTRS as being at least five years, but not more than 15 years, out of fellowship as of the deadline for the 2020 MCRA Letter of Intent (LOI).

OR

- Mid-career PhD researchers who propose collaborative research projects with at least one other eligible mid-career physician-scientist. “Mid-career PhD researchers” are defined as being at least five years, but not more than 15 years, following completion of a post-doctoral fellowship as of the deadline for the 2020 MCRA LOI. PhD researchers who have not yet received their first R01 level funding but have had a career development award are eligible to apply.

AND

- Have a history of career development award (CDA) funding: National Institutes of Health (NIH) K01, K08, or K23 awards, Canadian Institutes of Health Research (CIHR) Fellowship Program awards, or awards sponsored by foundations/societies (e.g. the HTRS Mentored Research Award (MRA) or NHF awards), or pharmaceutical companies (e.g. the Bayer Hemophilia Award or Pfizer Aspire). Applicants may apply during the final two years of a 5-year CDA.

Most MCRA applicants are Associate Professors or early professors. However, any faculty with a history of career development award funding (at the federal-level NIH K-series or CIHR Fellowship) who meet all eligibility criteria are welcome to apply. Applicants who have not held a career development award from the U.S. or Canada are not eligible.

Qualifying Hardships

HTRS will take appeals into consideration with regard to qualifying hardships. Examples include: a complete or partial hiatus from research activities for child rearing; an incapacitating illness or injury of the applicant or a member of the applicant’s immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors that would permit earlier retirement of debt incurred in obtaining a doctoral degree; and military service.

Potential applicants who do not meet the stated eligibility criteria with these or similar hardships are encouraged to contact Dr. Terri Holzen, HTRS Grants and Membership Manager at tholzen@versiti.org, HTRS@versiti.org, or 414-937-6569 to determine their eligibility to compete for an MCRA.

Ineligible Applicants

- Previous recipients of NIH Research Project Grants (R01), NIH Program Project Grants/Center Grants (P-Series), NIH Grants for collaborative research (U-Series), or equivalent grants from the NIH or elsewhere (e.g. CIHR: Project Grants and Foundation Grants).
- Applicants with a history of career development award (CDA) funding (NIH K01, K08 or K23 awards, CIHR Fellowship Program awards, Foundation/Society awards like the HTRS MRA) whose CDA ended more than four years ago.
- Applicants who have not held a career development award from either the U.S. or Canada
- Applicants who are less than five years out of fellowship

Additional Applicant Eligibility Requirements

- Applicants are required to be HTRS Core members at the time of LOI submission in good standing. Applicants agree to maintain HTRS Core memberships for the duration of the grant period and any approved no-cost extension (NCEs) if selected as MCRA recipients. (For more information about becoming an HTRS Core member, visit <https://www.htrs.org/HTRS/membership>.)
- Applicants must work in the U.S. or Canada for the duration of the grant period. U.S. or Canadian citizenship is not required
- Applicants must be employed at a university, hospital, hemophilia and/or thrombosis treatment center, or other non-commercial research institution in the U.S. or Canada. Applicants working for commercial research laboratories are not eligible to apply.
- Applicants must be able to devote at least 20% of their total time to the MCRA project, which may be supported in full or in part by the award funds.
- Previous HTRS Clinical Fellowship Award, HTRS Mentored Research Award, HTRS/ATHN DREAM Award, and THSNA (Thrombosis and Hemostasis Societies of North America) Mentored Research Award recipients may apply as long as they meet the stated eligibility criteria.
- Preference will be given to applicants who address critical issues in hemostasis and/or thrombosis in their projects, such as those described in the NHLBI Strategic Vision document (https://www.nhlbi.nih.gov/sites/default/files/2017-11/NHLBI-Strategic-Vision-2016_FF.pdf) and, specifically, the accompanying NHLBI Research Priorities found at: <https://www.nhlbi.nih.gov/about/strategic-vision/research-priorities>.

Questions Regarding Eligibility

Potential applicants are encouraged to contact Dr. Terri Holzen, HTRS Grants and Membership Manager at tholzen@versiti.org, HTRS@versiti.org or 414-937-6569 with specific questions about how their career path or previous research awards impact MCRA eligibility.

2020 MCRA Grant Period

The grant period for research projects funded through the 2020 MCRA Program is two (2) years.

- The earliest start date is November 1, 2020
- End date for projects launched on November 1, 2020 is October 31, 2022

Project Eligibility Requirements

Eligible research projects must involve a substantial component of hemostasis or thrombosis. Examples include, but are not limited to:

- Research in hemophilia, deep vein thrombosis (DVT), coagulation in sickle cell disease, mild or rare bleeding disorders, or uterine hemostasis relevant to heavy menstrual bleeding
- Other topics may be considered as long as they have a substantial component of, or overlap with, the disciplines of hemostasis or thrombosis (such as obstetrics/gynecology, adolescent medicine, neonatology, etc.)

Types of eligible projects include:

- Clinical/translational projects, including, for example, epidemiological studies or translational studies with or without a secondary component of laboratory work
- Translational/basic science projects, including, for example, molecular biology, physiology, pharmacology, or biomarker or translational studies where the primary emphasis is a laboratory component

Available Funding

The maximum 2020 MCRA over two (2) years is \$216,000 USD. This includes a maximum of \$200,000 for direct research project costs (\$100,000 per year) plus an additional maximum of \$16,000 (8% of \$200,000, or \$8,000 per year) for the recipient institution's indirect costs. (See the section "Use of MCRA Funds" in this RFP for more information regarding eligible indirect costs.)

An applicant's two-year MCRA project budget, including direct research project costs up to \$200,000 and indirect costs up to \$16,000, may not exceed a grand total of \$216,000 USD. **It is in the awardee's best interest if the budget total expenses are as close as possible to \$216,000 USD so that the total grant award is used.**

Funding of \$216,000 USD will be distributed by HTRS to the awardee's institution (the "recipient institution") in three payments:

- 1) The first payment of \$108,000 USD (50%) will be issued after full execution of the legal Grant Agreement contract between HTRS, the awardee, and the recipient institution.

- 2) The second payment of \$86,400 USD (40%) will be issued contingent upon acceptance by HTRS of a formal 12-month Progress Report describing research conducted during the first year of the grant period.
- 3) The third payment of \$21,600 USD (10%) is contingent upon acceptance by HTRS of a Final Report after the completion of the entire grant period. Instructions for compiling these reports will be communicated to the awardee or awardees in their formal notification letters and Grant Agreement contracts.

Use of MCRA Funds

MCRA grant funds (a grand total of \$216,000 USD) may only be applied to costs associated with proposed research project, including, but not limited to:

- Direct costs for the project not to exceed \$200,000 USD, such as:
 - Full or partial support for salary and fringe benefits for the investigator or other project personnel (laboratory technicians, statisticians, etc.)
 - Equipment and supplies necessary to conduct the research project
 - Registration, travel, and lodging fees for the investigator to attend a well-recognized national or international professional meeting during the duration of their project or in the year immediately following the grant period to present the progress or results of their MCRA-funded research. (MCRA funds may not be used to cover registration, travel, or lodging expenses to attend professional meetings outside of the above mentioned meeting, unless specifically approved by HTRS in advance as essential to the project outcome.)
- Indirect costs not to exceed \$16,000 USD, such as:
 - Lab fees, facility fees, or other costs related to the management of the funded research program by the recipient institution
 - The line item for indirect costs may not exceed 8% of the \$200,000 allocated to support the direct costs of the project, or \$16,000 over two years (or \$8,000 per year). An applicant's two-year MCRA project budget, including direct research project costs of \$200,000 and indirect costs up to \$16,000, may not exceed a grand total of \$216,000 USD

Current and Pending Support Requirements

MCRA applicants are required to report all current and pending funding sources for their proposed projects in the Full Proposal Narrative, budget, and within their NIH Biosketch.

Applicants are encouraged to apply to their institutional Office of Sponsored Research (OSR) for supplemental funds and support for their projects. However, in the event that additional funding becomes available, applicants will be asked to provide documentation to HTRS that line items supported by the MCRA Program do not overlap with support provided by other grants. If other grant funding covers all or substantially all of the costs of the MCRA project, any MCRA grant funds that remain unused must be returned to HTRS. Specific details of this requirement are included in the Grant Agreement contract.

Disclosure of HTRS Compliance with State or Federal Requirements per *Open Payments: The Physician Payments Sunshine Act*

HTRS research and fellowship awards may be reportable by law to state or federal agencies under *Open Payments: The Physician Payments Sunshine Act* (“Sunshine Act”). HTRS may be required to share information about recipient institutions, principal investigators, or other particulars of funded grants with the pharmaceutical companies that support our award programs. Such companies may deem grant information reportable per their policies related to the Sunshine Act.

Applicants to HTRS award programs are required to confirm, prior to submitting a proposal to HTRS that their institution is able to accept grant funding that may be subject to Sunshine Act reporting. Applicants who have questions about the Sunshine Act should ask their institutional Office of Research or other grant administrator for more detail, since regulations can differ by institution and state.

How to Apply for the 2020 MCRA

Formatting Instructions for Both the LOI and the Full Proposal

- Applicants must use an NIH-approved font (e.g. Arial, Georgia, Helvetica, or Palatino Linotype) for Letters of Intent (LOI) and Full Proposal Narratives, no less than 11 points in size. One-inch page margins are required for the Narratives and any references
- Single or double spacing is acceptable
- Only generic names of products/services are allowed; brand names and names of specific companies should not be used
- Applicants with questions related to these instructions should contact Dr. Terri Holzen, HTRS Grants and Membership Manager at tholzen@versiti.org, or HTRS@versiti.org or 414-937-6569 no later than one week in advance of the LOI deadline of March 20, 2020. LOIs and Full Proposals will be deemed ineligible for review if formatting instructions are not followed

Submitting a Letter of Intent

Letters of Intent (LOIs) are used by HTRS to guide the recruitment of appropriate expertise to the MCRA Study Section. It is in the applicant’s best interest to submit an informative LOI.

Applicants are required to follow all formatting instructions and submit the application to the HTRS online grant submission site on or before **Friday, March 20, 2020 at 11:59 p.m. ET**. The system will confirm receipt via email. **If you do not receive a confirmation email within 72 hours, please contact Dr. Terri Holzen, tholzen@versiti.org, for confirmation of receipt.**

Components of a Complete Letter of Intent

A. Required Application Form

Applicants are required to complete the 2020 MCRA Application Form available at the HTRS online grant submission site, <https://htrs.smapply.org>.

B. LOI Narrative (3 pages maximum, excluding references)

The three-page LOI Narrative should be addressed to the 2020 HTRS MCRA Program Chairs, Dr. Shannon Meeks and Dr. Jill Johnsen and include the following sections:

- 1) A statement of the applicant's overall scientific career goals and how the proposed MCRA project will facilitate the accomplishment of these goals. Applicants who are not working primarily as hematologists, but whose careers are in other disciplines that have a substantial component of, or overlap with the disciplines of hemostasis and/or thrombosis (e.g. obstetricians/gynecologists), must include a) the relevance of their proposed research to their career, b) how the disciplines of hemostasis and/or thrombosis overlap with and have substantial relevance to their career and c) how they will incorporate research and clinical care in hemostasis and/or thrombosis into their careers long-term.
- 2) A description of the significance and relevance of the proposed project, including the potential of the project to generate new knowledge in the field of hemostasis and/or thrombosis, and how the project will lead to larger-scale, independent research funding from the NIH or equivalent.
- 3) Hypotheses and aims/objectives of the proposed research.
- 4) The research plan. Please provide a clear description of how research will proceed. Briefly describe any preliminary data that you plan to include in the Full Proposal, as applicable.
- 5) Statistical plan and/or considerations. Statistical considerations and feasibility for the project must be addressed in the LOI, if only preliminarily.
- 6) A brief description of the appropriateness of the research environment as it pertains to the research project.
- 7) For PhD applicants, a clear explanation of the applicant's role vs. the role of the collaborator in the research

C. References (if applicable)

LOI Narrative references may be listed separately from the Narrative but should not exceed two additional pages. References must:

- Be relevant to the proposed project
- Be listed in the order in which they appear in the LOI

- List at least the first three authors. Using “et al.” in place of listing all authors of a reference is an acceptable practice.
- Include the applicant’s name in bold-face font if the applicant cites relevant references they authored.

LOI Review

After reviewing the LOIs, HTRS will confirm via email that applicants should submit a Full Proposal by the July 20, 2020 deadline. The goal of the 2020 MCRA Study Section is to invite all applicants who submit LOIs to submit Full Proposals unless:

- Applicant eligibility requirements are clearly not met
- The proposed project is not applicable to the field of hemostasis and/or thrombosis

Submitting a Full Proposal

The project outlined in the Full Proposal must be substantially the same as the project described in the LOI. Small modifications may be made, as long as the modifications are reasonable in scope (e.g. a change to or addition of a sub-aim).

Applicants are required to follow all formatting instructions and submit the Full Proposal to the HTRS online grant submission site (<https://htrs.smapply.org>) on or before **Friday, July 20, 2020 at 11:59 p.m. ET**. The system will confirm receipt via email. **If you do not receive a confirmation email within 72 hours, please contact Dr. Terri Holzen, tholzen@versiti.org, for confirmation of receipt.**

Components of a Complete Full Proposal

A. Required Application Form

Applicants must update the Application Form originally submitted with their LOI and include it as part of the full proposal submission.

B. Background and Career Description Statement (2 pages maximum)

- Description of the applicant’s background and preparation for the proposed research
- Statement of the applicant’s overall scientific career goals and how the proposed MCRA project will facilitate the accomplishment of these goals. Applicants who are not working primarily as hematologists, but whose careers are in other disciplines that have a substantial component of, or overlap with the disciplines of hemostasis and/or thrombosis (e.g. obstetricians/gynecologists), must include not only the relevance of their proposed research to their career, but also how the disciplines of hemostasis and/or thrombosis overlap with, and have substantial relevance to, their career

C. Project Narrative (10 pages maximum, excluding references)

The Project Narrative should address the following points. Reviewers will use these points as guidelines to assess the Full Proposal narrative.

- The significance and relevance of the project, including the potential of the project to generate new knowledge and how the project will lead to NIH or equivalent large-scale funding
- A clear statement of the hypothesis and specific aims/objectives for the proposed research, including a description of how those aims/objectives will be reached
- Experimental design and methodology, including potential limitations and a description of future studies to be pursued. The project design should be appropriate to test proposed hypotheses
- Project methods should support proposed aims. Preliminary data, if any, should be included
- Statistical plan and feasibility analysis, with patient or sample numbers and statistical methods identified
- If the research proposal requires additional funds, the narrative should describe the source of this funding (obtained or applied for) and should include a brief discussion of alternatives if funding is not secured
- Human subject or animal protections should be appropriately described, if applicable
- The application must clearly describe the nature of any professional collaborations and how this may affect the outcomes of the project. (Brief letters of support and NIH Biosketches should be appended to the application from all collaborators and/or co-investigators highlighting how their expertise will bring value to the proposed project.)
- A brief description of the quality of the research environment as it pertains to the project

D. References (if applicable)

References for the Full Proposal Narrative may be listed separately from the Narrative but should not exceed two additional pages. References must:

- Be relevant to the proposed project
- Be listed in the order in which they appear in the LOI
- List at least the first three authors. Using “et al.” in place of listing all authors of a reference is an acceptable practice.
- Include the applicant’s name in bold-face font if the applicant cites relevant references they authored.

E. Project Budget

The following expenses are permitted by HTRS as part of the project budget, which may not exceed (and should preferably be equal to) a total of \$216,000. It is in the awardee’s best interest if the budget total expenses are as close as possible to \$162,000 USD so that the total grant award is used.

Full Proposal applicants are required to use the Budget Template available for download from the HTRS online grant submission site at <https://htrs.smapply.org>. Applicants should provide a narrative explanation and justification for each line item requested in a separate addendum to the Budget Template.

1. Direct Project Costs not to exceed \$216,000 USD, including:

- Salary and fringe benefits for the applicant proportional to his/her percent effort on the project. Please compute the PI’s salary support as follows: Applicants must be able to devote at least

20% of their total time to the MCRA project, which may be supported in full or in part by the award funds. When computing salary support for the PI in the full proposal budget, please be aware that the 2019 NIH salary cap of \$192,300 will apply. Please refer to this link for information: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-099.html>

- Salary and fringe benefits for key personnel required to implement the research project
- Equipment and supplies necessary to fulfill the project's specific aims
- Registration, travel, and lodging fees for the investigator to attend a well-recognized national or international professional meeting during the duration of their project or in the year immediately following the grant period to present the progress or results of their MCRA-funded research. (MCRA funds may not be used to cover registration, travel, or lodging expenses to attend professional meetings outside of the above mentioned meeting, unless specifically approved by HTRS in advance as essential to the investigator's project outcome)
- Patient care costs if required for the study and not covered by third-party payments
- Human subjects payments
- Consultant costs for statistical or data management support

2. Indirect Costs not to exceed \$16,000 USD, including:

- Lab fees, facility fees, or other costs related to the management of the funded research program by the recipient institution
- The line item for indirect costs may not exceed 8% of the \$216,000 allocated to support the direct costs of the project, or \$16,000 over two years (\$8,000 per year). An applicant's two-year MCRA project budget, including indirect costs up to \$16,000, may not exceed and should be as close as possible to a grand total of \$216,000 (USD)

- F. A Letter of Support from the current department chairperson supporting the applicant's research and committing institutional support for the proposed project. This letter should include a statement of commitment to preserve and protect at least 20% of the applicant's total time for the proposed project. Due to the overall award cap (\$216,000 USD), an institutional commitment to match the proposal with uncompensated time and effort will be viewed favorably, as this will allow more of the grant budget to be spent on supplies, reagents, clinical research support, and other applicable project costs (i.e. <20% salary and fringe for the investigator is allowable in the project budget, but any remainder of the ≥20% salary and fringe should be accounted for in this letter of support)
- G. A copy of the applicant's current NIH Biosketch
- H. Letters of Support and NIH Biosketches for any collaborators and/or co-investigators

Full Proposal Review Process

Full Proposals will be reviewed by the MCRA Study Section using an NIH-style peer review process.

Any reviewer with a direct conflict of interest (such as involvement in any applicant's proposed project) is recused from the entire review process.

Any reviewer with an indirect conflict of interest (such as a close personal or professional relationship with any applicant, or previous involvement in any applicant's research) is recused from reviewing the specific application in question.

The MCRA Study Section performs the best possible Full Proposal review based on data submitted by each applicant. The goal is to select the most competitive MCRA proposal for funding. HTRS regrets that due to limited funding, it is not possible to award grants to all applicants. Final funding approval for the 2020 MCRA is granted by the HTRS Board of Directors.

Announcement of Award Recipients

The 2020 HTRS MCRA award recipient (or recipient team) will be announced in late September 2020. The earliest start date for the 2020 MCRA project is November 1, 2020.

Award funds will be disbursed within 30 days of the date of full execution of the legal Grant Agreement contract between HTRS and the awardee's institution.

Questions?

Questions about the 2020 HTRS MCRA Program should be directed to

Terri Holzen, PhD

Manager, Grants and Membership

Hemostasis and Thrombosis Research Society (HTRS)

414-937-6569

tholzen@versiti.org or htrs@versiti.org