

Request for Applications Hemostasis & Thrombosis Research Society (HTRS) 2025 HTRS Mid-Career Research Award (MCRA) Program

Letters of Intent (LOIs) are due Friday, August 30, 2024, by 11:59 PM ET Full Proposals are due Friday, December 13, 2024, by 11:59 PM ET

All applications must be submitted on the HTRS Online Grant Submission site

About the Hemostasis & Thrombosis Research Society

Incorporated as a nonprofit organization in 1994, the <u>Hemostasis & Thrombosis Research Society, Inc. (HTRS)</u> 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.

Program Goals

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

- Support investigator-initiated research to advance basic, translational, or clinical science research in hemostasis and/or thrombosis
- Combat the shortage of skilled academic researchers in classical hematology by supporting investigators in the U.S. and Canada at a critical juncture in their research careers
- Enable investigators to transition from mentored research to full research independence by providing needed financial support and protected time

Upon completion of an MCRA project, the recipient (or recipient team) should be ready to apply for a large-scale grant to expand their research such as an RO1 or equivalent from the National Institutes of Health (NIH) or other agency.

2025 MCRA Grant Period

The grant period for research projects funded through the 2025 MCRA Program is two (2) years:

- The earliest possible start date is July 1, 2025
- The earliest possible end date is June 30, 2027

Applicant Eligibility Requirements

PLEASE NOTE: If you are eligible for the <u>HTRS Mentored Research Award (MRA)</u>, HTRS strongly encourages you to apply for the MRA <u>before</u> applying for the MCRA.

Basic Eligibility Requirements

Eligible applicants must demonstrate a commitment to academic research careers in classical hematology and fulfill the following requirements:

- Have an MD, DO, PhD, MD/PhD, or equivalent doctoral degree
- Hold an academic faculty position at an institution in the U.S. or Canada
- Have had significant career development award funding
- Be working toward, and eligible to receive, a first R01 or equivalent in the U.S. or Canada
- Demonstrate a clear path by which the MCRA will support submission of an R01 or equivalent in the U.S. or Canada

Academic research careers in classical hematology are careers that have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis, such as hematology, pathology, transfusion medicine, obstetrics/gynecology, adolescent medicine, neonatology, etc.

Any applicant, regardless of rank, who meets all eligibility criteria is welcome to apply. Successful applicants are typically:

- Associate Professors (or equivalent) or Assistant Professors (or equivalent) with multiple years in rank
- Have eight (8) or more years' experience after training

Applicants with less than 5 years' or more than 15 years' experience after training at the time of the Letter of Intent (LOI) deadline are <u>not</u> eligible (see "Qualifying Life Events" for exceptions that may be considered upon appeal).

Definition of "Significant Career Development Award" Funding

Eligible applicants will have been the Principal Investigator (PI) of a career development award from the U.S. or Canada that has been successfully completed. Additionally, recipients of a 5-year career development award may apply for the MCRA in the final two years of the career development award. A qualifying career development award is a competitive postdoctoral award in the U.S. or Canada intended to support the early career of a researcher. Examples of qualifying career development awards include NIH K-awards, a CIHR Fellowship, the HTRS MRA, the ASH Junior Faculty Scholar Award, and their equivalents in Canada.

Additional Applicant Eligibility Requirements

- Applicants are required to be <u>HTRS Core Members</u> in good standing at the time of LOI submission.
 Applicants agree to maintain HTRS Core Membership for the duration of the grant period and any approved no-cost extension (NCEs) if selected as an MCRA recipient.
- 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 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.

Ineligible Applicants

The MCRA is intended to help investigators make the transition from career development awards to full research independence and R01-equivalent funding. The MCRA is <u>not</u> intended to be a bridge mechanism for established investigators.

An applicant is ineligible to apply for an MCRA if any of the following apply:

- Applicants who have been the PI (or equivalent) on any NIH Research Project Grant (R01), NIH Program
 Project Grant/Center Grant (P-Series), NIH Grant for collaborative research (U-Series), or equivalent
 grant from the NIH or elsewhere (e.g. CIHR: Project Grants and Foundation Grants) for which the
 Notification of Award date is prior to the full MCRA proposal deadline
- Applicants who have <u>not</u> held a career development award from either the U.S. or Canada
- Applicants who are <u>less than</u> five (5) years out of training
- Applicants who are more than fifteen (15) years out of training
- Applicants working for a commercial company

Qualifying Life Events

HTRS will consider appeals with regard to eligibility for qualifying life events. Examples include: a complete or partial hiatus from research activities for child rearing or caregiving; an incapacitating illness or injury affecting the applicant or a spouse, partner, or other close family member; 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.

Approved extension of NIH Early Stage Investigator (ESI) status can be accepted to extend eligibility for the MCRA for the same duration.

Potential applicants who do not meet the stated eligibility criteria and who wish to appeal with these or similar life events are encouraged to contact Jennifer Ziegler, HTRS Award Programs and Career Development Director at iziegler@htrs.org to determine their eligibility to apply for an MCRA at least two (2) weeks prior to the Letter of Intent due date.

Questions Regarding Eligibility

Potential applicants are encouraged to contact Jennifer Ziegler, HTRS Award Programs and Career Development Director at iziegler@htrs.org with questions about MCRA eligibility.

HTRS Commitment to Inclusivity

HTRS encourages applicants from historically excluded and underrepresented populations to apply, understanding that a diverse scientific workforce will, according to NIH research, foster scientific innovation, contribute to robust learning environments, improve the quality of the research, and advance the likelihood that underserved or health-disparate populations will benefit from this research.

This includes individuals from racial and ethnic groups who have been shown by the National Science Foundation to be underrepresented and/or historically excluded in health-related sciences on a national basis, as well as individuals with disabilities, applicants from low socioeconomic (SES) status backgrounds, individuals from disadvantaged backgrounds, and women.

HTRS bases our diversity policy on that of NIH's Interest in Diversity Notice.

In the MCRA application process, applicants will be offered the opportunity to self-identify as a member of an historically excluded and/or underrepresented population and provide a brief explanation.

Research 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 topics in 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

How to Apply for the 2025 MCRA

Formatting Instructions for LOIs and Full Proposals

All documents must use:

- An NIH-approved font (e.g., Arial, Georgia, Helvetica, or Palatino Linotype) of no less than 11 points in size
- A minimum of half-inch page margins
- Standard letter page size (8.5 x 11 inches)

Applicants should follow all instructions for each section, including page length requirements.

Only generic names of products/services are allowed; brand names and names of specific companies should not be used.

References should follow formatting standards that would be acceptable for an NIH application.

LOIs and Full Proposals will be deemed ineligible for review if formatting instructions are not followed.

SUBMITTING A LETTER OF INTENT (Required)

MCRA Letters of Intent (LOIs) are used to assess eligibility and 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.

LOI Due Date

LOIs must be submitted via the HTRS online grant submission site on or before **Friday**, **August 30**, **2024**, **by 11:59 PM ET.** The system will confirm receipt of submission via email. <u>If you do not receive confirmation of receipt via email within 72 hours, please contact jziegler@htrs.org.</u>

Components of the LOI

A. LOI Form

Applicants are required to complete the 2025 MCRA LOI Form available at the <u>HTRS Online Grant Submission site</u>.

B. LOI Narrative Letter (2 pages maximum)

The LOI Narrative Letter should be addressed to the 2025 HTRS MCRA Program Chairs, Drs. Jill Johnsen and Janice Staber, and include the following sections:

1) Applicant's Career Statement

This is a statement of the applicant's scientific career goals and how the proposed MCRA project will facilitate their accomplishment. This description should also include the relevance of the proposed research to the applicant's career goals and how the disciplines of hemostasis and/or thrombosis have substantial relevance to the applicant's career and long-term goals.

2) Research Project's Relevance to Hemostasis and/or Thrombosis

This is 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.

3) Pathway to R01 (or equivalent) Award

This is a description of how the MCRA project will lead to larger-scale, independent research funding, such as an NIH R01 or equivalent.

4) Specific Aims

The specific aims should concisely describe the goals and objectives of the proposed research and summarize the expected outcomes and impact of the results for the field.

C. NIH Biosketch

The applicant's NIH Biosketch should follow the current NIH format at the time of submission.

D. Other Support

All current and pending support, including training grants and gifts, should be reported in the Other Support document. This document should otherwise follow NIH formatting guidance.

Letter of Intent Review

The goal of LOI review is to determine whether the applicant and research topic are eligible for the MCRA, as outlined above. After LOI review, qualifying applicants will be invited via email to submit a Full Proposal. Notifications are expected to be sent to applicants on or before **October 1, 2024**.

Reasons applicants would not be invited to submit a full proposal are:

- 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 proposed in the Full Proposal must be substantially the same as the project relevant to hemostasis and/or thrombosis that was 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).

Full Proposal Due Date

The Full Proposal must be submitted to the <u>HTRS online grant submission site</u> on or before **Friday**, **December 13, 2024**, at **11:59 PM ET.** The system will confirm receipt of submission via email. <u>If you do not receive a confirmation of receipt via email within **72** hours, please contact jziegler@htrs.org.</u>

Components of the Full Proposal

A. Full Proposal Application Form

Applicants must complete the 2025 MCRA Full Proposal Form available at the <u>HTRS Online Grant</u> Submission site.

B. Applicant's Background and Career Statement (2 pages maximum)

The Applicant's Background and Career Statement should be a personalized statement written by the applicant that should:

- Describe the applicant's background and preparation for the proposed research
- State the applicant's overall scientific career goals and how the proposed MCRA project will facilitate the accomplishment of these goals
- Describe a plan to advance career goals
- Address the applicant's commitment to an academic research career in classical hematology
- Describe how hemostasis and/or thrombosis has substantial relevance to the applicant's career
- Describe how the proposed MCRA project fills a critical gap needed to obtain R01-level funding

C. Research Plan (10 pages maximum, excluding references)

The Project Research Plan should address the points below. Applicants should consider that reviewers will be instructed to assess the merits of the application using six (6) criteria (see also Full Proposal Review Process, below):

- 1. The significance and relevance of the project, including the potential of the project to generate new knowledge
- 2. 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
- 3. 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
- 4. Project methods should support proposed aims. Preliminary data, if any, should be included
- 5. Statistical plan and feasibility analysis, with patient or sample numbers and statistical methods identified
- 6. A 2-year timeline for the proposed research
- 7. 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
- 8. Human subject or animal protections should be appropriately described, if applicable
- 9. 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 highlighting how their expertise will bring value to the proposed project.)
- 10. A brief description of the quality of the research environment as it pertains to the project

E. References (No page limit)

References should be listed separately from the Research Plan. References must:

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

- 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 have authored

F. MCRA Budget

Two budget documents are required:

- Completed <u>Budget Template</u> (available on the <u>HTRS online grant submission site</u>).
- <u>Budget Justification</u>. This is a narrative explanation and justification for each line item requested in the Budget Template.

The following costs are permitted in the MCRA budget:

- 1. <u>Direct project costs</u> not to exceed \$200,000 USD total over the two-year period of the award, including:
 - Salary and fringe benefits for the applicant (PI). Consider the following when computing salary support:
 - The applicant (PI) 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.
 - Salaries should use the current <u>NIH salary cap</u> at the time of full proposal submission.
 - Full or partial support for salary and fringe benefits for other project personnel (laboratory technicians, statisticians, etc.)
 - Equipment, supplies, and services 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 to present the progress or results of their MCRA-funded research
 - Patient care costs if required for the study and not covered by third-party payments or other funds
 - Human subjects incentives, IRB fees, and other human subjects research costs
 - Animal and vivarium costs
 - Consultant costs for statistical, data management, or computing support
- Indirect costs, not to exceed 8% of the total Direct Costs (\$16,000), including facility fees, administrative support, office supplies, or other costs related to the management of the funded research program by the recipient institution. Example: A project with total direct costs of \$200,000 (\$100,000 per year for two years) can charge indirect costs of up to \$16,000 (\$8,000 per year for two years).

G. Institutional Letter of Support

A letter from the applicant's current Department Chair supporting the proposed 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 for additional time and effort

support will be viewed favorably as this will allow more of the grant budget to be spent on supplies, reagents, and other applicable project costs.

H. NIH Biosketch

The applicant's NIH Biosketch should be updated from the one submitted in the LOI, as appropriate.

I. Other Support

All current and pending support, including training grants and gifts, should be reported in the Other Support document and be current as of the time of full proposal submission.

J. Letters of Support and NIH Biosketches for collaborators and/or co-investigator

Full Proposal Review Process

Each MCRA full proposal application is reviewed by independent expert reviewers. The HTRS MCRA requires all reviewers to declare conflicts of interest and manages conflicts in-line with NIH policies.

The HTRS MCRA review process adapts the NIH framework for reviewing awards. Reviewers will use the five NIH criteria (Significance, Investigator, Innovation, Approach, Environment) and an additional MCRA-specific criteria called Pathway to Independence. The Pathway to Independence criteria evaluates if the applicant has demonstrated a clear path by which MCRA-support will lead to a competitive independent extramural grant application (e.g. NIH R01 or equivalent).

Final funding approval for the 2025 MCRA is granted by the HTRS Board of Directors. HTRS regrets that due to limited funding it is not possible to award grants to all applicants.

Announcement of Award Recipients

The 2025 HTRS MCRA recipient will be announced before April 2025. The earliest start date for the 2025 MCRA project is July 1, 2025.

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.

HTRS reserves the right to postpone decisions regarding the 2025 MCRA Program and/or cancel the 2025 MCRA prior to announcing awards based on the status of HTRS fundraising for the Program.

Other Information for MCRA Applicants and Awardees

Additional New Funding

In the event that additional funding becomes available to the applicant *after* submission of the full MCRA proposal, HTRS must be notified within 14 business days of the Notification of Award issuance or award start date, whichever occurs first. The notification to HTRS of new support should include:

- The applicant's current NIH Biosketch and Other Support
- Explanation of scientific overlap (or statement of no overlap) between the MCRA and new award
- If there is scientific overlap, explanation of budgetary overlap (or statement of no overlap with detailed justification) between the MCRA and the competing R01 (or equivalent)
- In the event of budgetary overlap, a revised detailed MCRA budget with budget justification for review

Concurrent Awards

Prior HTRS approval is required in order for the applicant to hold awards concurrently.

Other Changes or Withdrawal

If the applicant wishes to notify HTRS of any other new events or to withdraw their application, the applicant should notify HTRS as soon as possible by emailing jziegler@htrs.org.

MCRA Award Funding Disbursement Schedule

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

- 1) The first payment of up to \$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 up to \$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 up to \$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 in their formal notification letters and Grant Agreement contracts.

Questions?

Questions about the 2025 HTRS MCRA Program can be directed to:

Jennifer Ziegler
Director, Award Programs and Career Development
Hemostasis and Thrombosis Research Society (HTRS)
jziegler@htrs.org