



Request for Proposals (RFP) Hemostasis and Thrombosis Research Society (HTRS) 2019 HTRS Mentored Research Award (MRA) Program

- **2019 MRA Pre-proposal deadline extended to Friday, September 7, 2018 by 6:00 p.m. ET**
- **2019 MRA Full Proposals (by invitation only) are due Tuesday, December 18, 2018 by 6:00 p.m. ET**
- **Proposals should be submitted as one PDF document to htrs@bcw.edu**

About HTRS

Incorporated as a nonprofit organization in 1994, the Hemostasis and Thrombosis Research Society (HTRS) is a North American professional medical society dedicated to advancing care for people with bleeding and thrombotic disorders through investigator-initiated research, mentoring, and continuing medical education. To learn more about HTRS, visit www.htrs.org.

About the HTRS Mentored Research Award Program

The HTRS Mentored Research Award (MRA) Program provides financial support for qualified fellows or junior attending/junior faculty pursuing clinical, translational, or basic science research projects in hemostasis and/or thrombosis under the guidance of an experienced mentor. Since the program's inception in 2007, HTRS has awarded more than \$6.5 million for 42 Mentored Research Awards.

The goals of the HTRS MRA Program are to:

- **Combat the shortage of skilled academic physician researchers in non-malignant hematology in North America** by providing funding, mentorship, and career development support to early stage physician scientists pursuing academic research careers in non-malignant hematology (or areas of medicine with a major component of non-malignant hematology).
- **Advance the science underlying the clinical management of hemostasis and thrombosis disorders** by supporting new research to improve the health and well being of people living with these disorders.

The grant period for research projects funded through the 2019 MRA Program is two academic years, from July 1, 2019 through June 30, 2021. (The administrative program cycle for the 2019 MRA Program is July 1, 2019 through December 31, 2021.) The maximum MRA for 2019 is \$162,000 USD (\$81,000 per year for two years). This includes a maximum of \$150,000 for direct research project costs (\$75,000 per year) plus an additional maximum of \$12,000 (8% of \$150,000 or \$6,000 per year) for recipient institution program management fees or indirect costs.

An applicant's two-year MRA project budget, including program management fees/indirect costs of up to \$12,000, may not exceed and should be as close as possible to a grand total of \$162,000 USD.

HTRS reserves the right to determine the number and category of grants awarded through the 2019 MRA Program (i.e. hemostasis vs. thrombosis, clinical vs. translational vs. basic science) based on the number and quality of submitted proposals, the availability of grant funding to HTRS, and/or therapeutic focus areas of MRA Program supporters.

Application for a 2019 HTRS MRA is a two-step process:

Step 1: Pre-proposal Submission

Applicants are required to submit a Pre-proposal to be reviewed by the HTRS Scientific Review Committee. The deadline to submit 2019 MRA Pre-proposals is **Friday, September 7, 2018 by 6:00 p.m. ET**. For complete Pre-proposal preparation and submission instructions, see page 10 of this RFP.

Applicants whose Pre-proposals are favorably reviewed will be invited to submit Full Proposals on or before **Tuesday, December 18, 2018 at 6:00 p.m. ET**. (See Step 2: Full Proposal Submission, below, for more information.)

Please be aware that invitations to submit Full Proposals will not be distributed until approximately two months following the Pre-proposal submission deadline (in late September) to allow adequate time for the Pre-proposal review process over the summer months.)

Step 2: Full Proposal Submission (Invited Applicants Only)

Applicants whose Pre-proposals are favorably reviewed will be invited to submit Full Proposals on or before **Tuesday, December 18, 2018 at 6:00 p.m. ET**. Please note that this deadline may be readjusted due to reviewers' schedules; in this case, Full Proposal applicants will receive notification of the new due date via email.

Also note that the project outlined in the Pre-proposal must be substantially the same as the project described in the Full Proposal. For complete Full Proposal preparation and submission instructions, see page 12 of this RFP.

Applicant Eligibility Requirements

Eligible applicants must hold an MD or DO and be either:

1. A fellow:
 - a. In training for a career in hemostasis and/or thrombosis
- OR**

- b. In training for a career that will have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis

OR

2. A junior attending or junior faculty:

- a. Within seven years of completing training for a career in hemostasis and/or thrombosis as of July 1, 2019

OR

- b. Within seven years of completing training for a career that will have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis as of July 1, 2019

Exceptions to the seven year requirement may be made for applicants who provide a legitimate explanation for being more than seven years out of fellowship, such as taking time off to raise children or the decision to move from another area of medicine to non-malignant hematology. Applicants who believe they may be exempt from the seven year requirement should email an explanation to htrs@bcw.edu so that a determination may be made as to eligibility before time is spent preparing a Pre-proposal.

Additional Applicant Eligibility Requirements

- HTRS offers all fellows/trainees free HTRS membership for the duration of their fellowship, and applicants who are fellows/trainees are required to activate their free membership at www.htrs.org no later than the Pre-proposal deadline of **Friday, September 7, 2018 at 6:00 p.m. ET** in order to be eligible for an award. Applicants who are junior faculty/junior attending are strongly encouraged (but not required) to become HTRS members prior to submitting an MRA Pre-proposal. (Membership status will not affect recipient selection.) Applicants agree to maintain active HTRS memberships for the duration of the grant period if selected as MRA recipients.
- Fellows must be enrolled in accredited fellowship training programs in the United States or Canada. Note to Canadian applicants: Due to restrictions imposed by U.S. pharmaceutical companies supporting the MRA, HTRS may not be at liberty to fund Canadian fellows or junior attending/junior faculty in 2019. However, every year since the inception of the MRA we have had at least one to two awards available to Canadian applicants and we are hopeful this will remain the case. In fact, this past year was the first year an award was granted to a Canadian. Interested Canadian applicants should email HTRS at htrs@bcw.edu prior to taking the time to submit a Pre-proposal in order to inquire if they are eligible for funding.
- Junior attending/junior faculty applicants must hold a faculty position in a U.S. (or Canadian, if applicable) academic institution.
- Only applicants and mentors associated with non-commercial institutions are eligible. Applicants must declare their intent to pursue an academic career in hemostasis and/or thrombosis or an academic career that will have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis.
- U.S. or Canadian citizenship is not required, but Awardees must work in the U.S. or Canada for the duration of the grant period.
- Awardees may be enrolled in a higher degree program during the tenure of the MRA as long as they demonstrate that they have sufficient time to conduct the research program proposed in their application. (Awardees are expected to devote at least 20% of their total time to the Project. See pages 7-8 for further information.)

Eligibility Regarding Applying for More than One HTRS Award

- Previous HTRS MRA or THSNA (Thrombosis and Hemostasis Societies of North America) MRA recipients are not eligible to apply.
- Applicants for any of the past HTRS or THSNA MRAs who have not been selected for an MRA and who meet the eligibility requirements may submit a Pre-proposal for the 2019 HTRS MRA with the same or a different institution/laboratory, the same or a different mentor, and the same or a different project used for their previous HTRS MRA application. If an applicant submits an application for the same project, reviewers will look for improvements based on past reviewer comments, if comments were provided. (Reviewer comments are only provided at the Full Proposal stage.)
- Previous HTRS Clinical Fellowship Award or HTRS/ATHN DREAM Award applicants or recipients who meet the eligibility requirements may apply.
- Applicants considering applying for more than one HTRS award with overlapping grant periods in a given year should contact HTRS at HTRS@bcw.edu to discuss before preparing the applications. (Applicants generally may not receive more than one HTRS award with overlapping grant periods in a given year.)

Mentor Eligibility Requirements and Letters of Support

Applicants are required to select a primary mentor who is an experienced researcher (MD, DO, and/or PhD) in hemostasis and/or thrombosis. Mentors must agree to supervise the applicant and accept the conditions of the award.

Although typically the applicant's primary mentor and/or co-mentor are present at the same institution where the applicant proposes to do the majority of the proposed research, applicants may have a mentor and/or co-mentor at a different institution as long as an effective communication plan is outlined in the Pre-proposal and Full Proposal applications to indicate how the mentoring will be accomplished over distance.

The primary mentor must:

1. Work in hemostasis and/or thrombosis (i.e. directly involved in clinical, translational, and/or basic science research pertaining to bleeding and/or thrombotic disorders)
OR
2. Work in another area of medicine that has a substantial component of, or overlap with, hemostasis and/or thrombosis
AND
3. Agree to become an HTRS member, if not a member already. The mentor must submit a membership application at www.htrs.org no later than the Pre-proposal deadline of **Friday, September 7, 2018 at 6:00 p.m. ET**. If the applicant is selected as an MRA recipient, the mentor agrees to maintain active membership for the duration of the grant period.

In addition to securing a primary mentor with the above credentials, applicants may also select a co-mentor who provides additional medical or scientific expertise. Co-mentors are not required to be HTRS members and may be MDs, DOs, or PhDs. Applicants are not required to secure a co-mentor to be eligible for an award.

If the applicant is invited to submit a Full Proposal, formal letters of support are required from the primary mentor and the co-mentor (if applicable), as well as from the appropriate institutional official (department chair or division chief) indicating institutional commitment of sufficient time to permit the applicant to conduct the

research. (See pages 13-14 for further requirements for the letters of support.) HTRS believes that young Awardees need a substantial amount of protected time for research in order to have a quality learning experience and ensure project outcomes. Therefore, HTRS encourages the recipient institution to protect a minimum of 50% of the Awardee's total time for research or research-related activities. However, HTRS requires the institution to protect a minimum of 20% of the Awardee's total time for the HTRS MRA Project itself. (See pages 7-8 for further information regarding time commitment.)

Project Eligibility Requirements

Eligible research projects should involve a substantial component of hemostasis and/or thrombosis. Examples include, but are not limited to, the study of hemophilia, deep vein thrombosis (DVT), coagulation in sickle cell disease, mild or rare bleeding disorders, uterine hemostasis relevant to heavy menstrual bleeding, etc. Hemostasis/thrombosis topics in areas that have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis (such as obstetrics/gynecology, adolescent medicine, neonatology, etc.) are eligible.

Eligible research projects include:

1. **Clinical/Translational projects**, including, for example, epidemiological or translational studies with or without a secondary component of laboratory work
OR
2. **Translational/Basic science/Laboratory projects**, including, for example, molecular biology, physiology, pharmacology, biomarker, or translational studies where the primary emphasis is a laboratory component

Interested applicants should email htrs@bcw.edu prior to taking the time to submit a Pre-proposal if there are any questions regarding whether a project is eligible or not.

Available Funding

The maximum MRA for 2019 is \$162,000 USD (\$81,000 per year for two years). This includes a maximum of \$150,000 for direct research project costs (\$75,000 per year) plus an additional maximum of \$12,000 (8% of \$150,000 or \$6,000 per year) for recipient institution program management fees or indirect costs. An applicant's two-year MRA project budget, including direct research project costs of up to \$150,000 and program management fees/indirect costs of up to \$12,000, may not exceed and should be as close as possible to a grand total of \$162,000.

Funding of \$162,000 USD will be distributed by HTRS to the recipient institution in three payments:

1. The first payment of \$81,000 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 \$64,800 USD (40%) will be issued after approval by HTRS of a formal 12-month Progress Report (Narrative and Financial Reports) describing research conducted during the first year of the grant period.
3. The third payment of \$16,200 USD (10%) is contingent upon approval by HTRS of a Final Report (Narrative and Financial Reports) after the completion of the entire grant period.

Instructions for reporting requirements are communicated to successful applicants in their award notification letters and Grant Agreement contracts.

HTRS reserves the right to postpone decisions regarding the 2019 MRA Program and/or cancel any or all 2019 MRAs prior to announcing awards based on the status of HTRS fundraising for the Program.

Use of MRA Funds

MRA funds must be used to support costs associated with the proposed research project, including, but not limited to:

1. Direct Project costs not to exceed \$150,000, such as:
 - Full or partial support for salary and fringe benefits for the Awardee and/or other key project personnel (laboratory technicians, statisticians, etc.)
 - Equipment and supplies necessary to conduct the research project
 - Registration, travel, and lodging fees for the Awardee to attend a well-recognized national or international professional meeting during the duration of their project or in the year immediately following the project period to present the progress or results of their MRA-funded research. (See page 7 for further instructions regarding this requirement.) MRA 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 Awardee's project outcome.

2. Program Management Fees/Indirect Costs not to exceed \$12,000:

This covers program management fees (including lab or facility fees) or indirect costs as required by the recipient institution. The line item for these fees may not exceed 8% of the \$150,000 allocated to support the direct costs of the project, or \$12,000 over two years (\$6,000 per year). An applicant's two-year MRA project budget, including research project direct costs of \$150,000 and program management fees/indirect costs of up to \$12,000, may not exceed and should be as close as possible to a grand total of U.S. \$162,000.

Current and Pending Support Requirements

Invited MRA Full Proposal applicants must report all current and pending funding sources for their proposed projects in their Full Proposals. Applicants are encouraged to apply to their institutional Office of Sponsored Research (OSR) for supplemental funds and support. However, in the event that additional funding becomes available to cover salary/fringe benefit support or other direct research costs, Awardees will be asked to provide documentation to HTRS that line items supported by the MRA Program do not overlap with support provided by other grants. If the new funding covers all or substantially all of the costs of the project, any awarded MRA grant funds that remain unused must be returned to HTRS. Specific details of this requirement are included in the Grant Agreement contract.

Statistical Support Requirements

All applicants are required to identify resources for obtaining statistical support for a) writing their full proposal b) implementing their project if selected for an MRA. Applicants without access to adequate institutional or other local statistical support are strongly encouraged to request complimentary support from HTRS to develop

their research study design and statistical plan, which is required for the Full Proposal. Such applicants must include the request and the detailed reasons for the request in their Pre-proposals. However, assistance with the statistical portion of the project implementation, if the applicant is selected as an MRA recipient, is not available and applicants must indicate a plan as to where they will obtain statistical support for project implementation.

If statistical support is requested from HTRS to develop the Full Proposal, and the Pre-proposal is favorably reviewed, a statistical consultant will contact the applicant directly to assist in the preparation of their Full Proposal. Statistical services to applicants include guidance for: establishing study goals and objectives/hypotheses, identifying appropriate study design (clinical trial, epidemiologic, cross-sectional, longitudinal, single center, multi-center); deciding on the type and amount of data to collect; determining appropriate sample size; and methods for analyzing data and reporting results. The biostatistician is extensively trained in advanced methods of statistical analysis. Past MRA applicants have indicated that services provided by the statistical consultant were of very high quality.

HTRS believes that introducing young investigators to a structured process for approaching statistical planning will better prepare them to carry their research forward to additional competitive funding (e.g. NIH) and help them develop other project plans and grant applications in the future.

Presentation Requirements for MRA Awardees

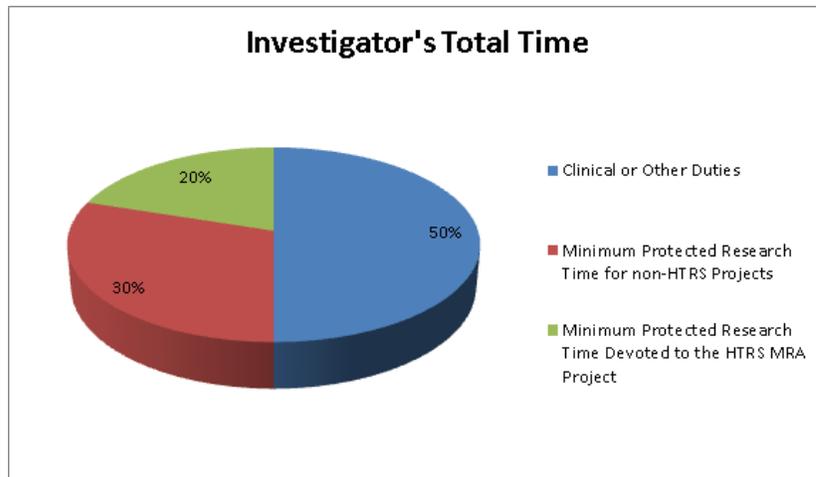
Awardees are required to make a good faith effort to present information about the project's research progress or outcomes at a well-recognized national or international professional meeting during the two-year grant period or in the year immediately following the grant period. The Awardee is encouraged to select the HTRS Scientific Symposium as the meeting of choice to fulfill this requirement, with the Thrombosis and Hemostasis Societies of North America (THSNA) Summit as a second choice. Funds to support conference registration fees, travel, and lodging for this meeting should be calculated into the total MRA grant budget. Instructions for acknowledging HTRS and the grant's industry supporter in any presentations will be included in the successful applicant's notification letter and/or Grant Agreement contract.

Other Conditions and Responsibilities

Submission of a 2019 MRA Pre-proposal and invited Full Proposal implies acceptance of the following conditions by the applicant, the recipient institution, and mentor and co-mentor:

1. **Focus of the MRA Award.** The principal focus of the MRA is to enable the successful applicant to further his/her experience in performing clinical, translational, or basic science research in hemostasis and/or thrombosis. HTRS believes that early career awardees have an increased chance of a quality learning experience and successful project outcomes when at least half (50%) of their total time is protected by their institutions for research or research-related activities. Therefore, HTRS encourages the recipient institution to protect a minimum of 50% of the Awardee's total time for research or research-related activities. However, HTRS requires the institution to protect a minimum of 20% of the Awardee's total time for the HTRS MRA Project itself.

For example, in a 40 hour work week, HTRS encourages the institution to protect at least 20 hours (50%) of the 40 hours for research and research-related activities, and requires at least 8 hours (20%) of the 40 hours for the MRA project.



2. Required Grant Agreement Contract. Upon notification of an MRA award, Awardees are responsible for providing HTRS with the name and contact information of the appropriate financial or legal representative at the recipient institution who should receive the Grant Agreement contract. The Awardee, his/her primary mentor and co-mentor, the recipient institution's representative, and an HTRS representative are required to sign a Grant Agreement contract prepared by HTRS before award funds are dispersed.
3. Change in Status. The Awardee is responsible for providing HTRS with written notice of any Change in Status related to their project or career path at any time during the course of the project period. Change in Status notification letters are subject to review and approval by HTRS. While most change requests are negotiable, it should be noted that a change in career direction from an academic research institution to a commercial research laboratory, for example, is not permitted per MRA eligibility requirements and will result in the returning the balance of his/her MRA funding to HTRS. The exact conditions and instructions for submitting a Change in Status request are outlined in the Grant Agreement contract.
4. Award Administration. The day-to-day administration of MRA award funds is the responsibility of the recipient institution's OSR or hospital research department. As such, the recipient institution issues award funds as outlined in the approved project budget according to its own procedures and payment schedules. Funds are not sent to Awardees directly.
5. Requirements Regarding Rights of Human Subjects. The recipient institution is responsible for protecting the rights and welfare of all human subjects participating in the MRA-funded research activity. Awardees requesting MRA funds for research involving human subjects are required to submit written evidence of Institutional Review Board (IRB) approval, along with written evidence of their institution's Federalwide Assurance (FWA) number (for U.S. investigators) and renewal date to HTRS before funding can be awarded. These approvals must be in place for the duration of the grant period in order to continue to receive MRA funding from HTRS and will be appended to the fully executed Grant Agreement contract. Written evidence of continuing IRB approval and FWA renewal (FWA renewal is every five years) will need to be submitted with each Progress Report to confirm continued coverage.
6. Requirements Regarding Animal Studies. The recipient institution is responsible for protecting the welfare of animals involved in the MRA-funded research activity. Awardees requesting MRA funds for research involving animals are required to submit written evidence of Institutional Animal Care and Use

Committee (IACUC) approval, along with a copy of their institution's Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International accreditation to HTRS before funding can be awarded. These approvals must be in place for the duration of the grant period in order to continue to receive MRA funding from HTRS and will be appended to the fully executed Grant Agreement contract. Written evidence of continuing IACUC approval and AAALAC accreditation (AAALAC review is every three years) will need to be submitted with each Progress Report to confirm continued coverage.

7. Acknowledgment of HTRS and Pharmaceutical Company Support. Any articles (published and in progress), abstracts, or oral and poster presentations resulting from the Awardee's MRA-funded research must acknowledge both the support of HTRS and the appropriate pharmaceutical industry supporter as outlined in the applicant's award notification letter and/or the fully executed Grant Agreement contract. Awardees are required to provide HTRS with a copy of any articles (published and in progress), abstracts, or oral and poster presentations resulting from their MRA-funded research during and after the grant period with the appropriate acknowledgments listed.
8. Required Reports. Per the fully executed Grant Agreement contract, Awardees are required to submit two formal reports using templates provided by HTRS: 1) a Progress Report describing the first year of MRA-funded research, and 2) a Final Report to be submitted within three months of the completion of the grant period. HTRS is required to share these reports with pharmaceutical company supporters. As such, Awardees should prepare their reports to include supporter acknowledgment as outlined in their Grant Agreement contracts.

Required reports also must include a list of any articles (published and in progress), abstracts, or oral and poster presentations resulting from the MRA-funded research, with copies of articles (published and in progress), abstracts, or oral and poster presentations appended. Awardees accept primary responsibility for understanding when reports are due and for following submission instructions provided by HTRS.

- a. Progress Report: This report consists of two parts: a Narrative Report of progress made during the first year of MRA-funded research prepared by the Awardee, and a Financial Report outlining first year expenses as prepared by the recipient institution's OSR or hospital research department. Both reports must be submitted using the required templates provided by HTRS to the Awardee and recipient institution upon full execution of the Grant Agreement contract.

The second payment of the Grant is contingent upon: 1) satisfactory progress having been made during the first year, as determined by HTRS, per the hypotheses and aims outlined in the original application, and 2) acceptance by HTRS of first year expenses as submitted by the recipient institution's OSR or hospital research department, compared to the most current approved version of the project budget. Unless other arrangements are made in advance, HTRS reserves the right to delay or withhold the second payment if: 1) the Progress Report is not submitted by the deadline listed in the Grant Agreement contract, or 2) evidence of satisfactory progress, as determined by the HTRS Scientific Review Committee, has not been made on the Project's aims.

- b. Final Report: This report consists of two parts: a Narrative Report of progress made over the entire grant period and a Financial Report outlining expenses incurred during the entire grant period. Both reports must be submitted using the required templates provided by HTRS to the Awardee and recipient institution upon full execution of the Grant Agreement contract.

The third and final payment of the Grant is contingent upon: 1) satisfactory progress having been made during the tenure of the grant as determined by HTRS, per the hypotheses and aims outlined in the original application; and 2) acceptance by HTRS of project expenses submitted by the recipient institution's OSR or hospital research department, as compared to the most current approved version of the project budget. Unless other arrangements are made in advance, HTRS reserves the right to delay or withhold funds for the third and final payment if: 1) the Final Report is not submitted by the deadline listed in the Grant Agreement contract, or 2) evidence of satisfactory progress, as determined by the HTRS Scientific Review Committee, has not been made on the Project's aims.

Preparing a Pre-proposal

Pre-proposals are a mandatory first step in the MRA submission process. Applicants are required to follow all formatting instructions and incorporate both the Application Form and the Pre-proposal Narrative (described below) into one PDF document and submit it to htrs@bcw.edu on or before **Friday, September 7, 2018 by 6:00 p.m. ET**. HTRS will confirm receipt via return email. **If you do not receive a confirmation email within 72 hours, please contact us at 414-937-6569.**

Components of a Complete Pre-proposal

1. Application Form

Applicants are required to complete the Application Form in writable PDF format that will become available at www.htrs.org by June 2018. Applications that do not include this required form will not be accepted.

2. Pre-proposal Narrative (3 pages maximum, excluding references)

Although every effort is made to match reviewers' expertise to the type of proposal submitted, please prepare your narrative with the assumption that an academic or clinical hematologist may review your application (as opposed to a specialist in basic or laboratory science, for example).

The three-page Pre-proposal Narrative should address the points listed below, insofar as space permits, and be clear, concise, and well-written. Reviewers will use these points as guidelines to assess the quality of the a) applicant; b) mentor(s) and environment; c) science; and d) research plan.

a. **Quality of applicant** should include:

- i. Background of the applicant
- ii. Demonstrated sincere commitment to an academic career in non-malignant hematology and/or an academic career with a major component of, or overlap with, non-malignant hematology
- iii. Relevance of the proposed research to the applicant's stated career goals
- iv. Applicants who are not training or working primarily as hematologists, but whose careers in other disciplines have a substantial component of, or overlap with, the disciplines of hemostasis and/or thrombosis (e.g. obstetricians/gynecologists) should describe not only the relevance of the proposed research to their career, but also how the disciplines of hemostasis and/or thrombosis overlap with, and have substantial relevance to, their career.

- b. **Quality of mentor(s) and environment** should include:
- i. Description of the primary mentor and co-mentor's qualifications
 - ii. Quality and appropriateness of the research environment as it pertains to the applicant and project
 - iii. A clear explanation of the applicant's role vs. the role of the primary mentor and co-mentor in the research concept, design, and implementation. If relevant, specify the specific parts of the project to be carried out by the applicant as opposed to the primary mentor and co-mentor
 - iv. If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance
- c. **Quality of the science** should include:
- i. Background, scientific merit, significance, and impact of the project
 - ii. Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects.
- d. **Quality of the research plan** should include at least brief reference to the following, with one or more aspects presented in greater detail. It is understood that where greater detail is provided may vary with the specific proposal:
- i. Hypotheses and aims/objectives of the proposed research
 - ii. Study design and methodology
 - iii. Discussion of feasibility
 - iv. Potential limitations and how to address them
 - v. Statistical plan and/or considerations, if only preliminarily. If applicable, preliminary data should be included.
 - vi. Plan for obtaining statistical support. All applicants are required to identify resources for obtaining statistical support for a) writing their full proposal b) implementing their project if selected for an MRA. Applicants without access to adequate institutional or other local statistical support are strongly encouraged to request complimentary support from HTRS to develop their research study design and statistical plan, which is required for the Full Proposal. Such applicants must include the request and the detailed reasons for the request in their Pre-proposals. However, assistance with the statistical portion of the project implementation, if the applicant is selected as an MRA recipient, is not available and applicants must indicate a plan as to where they will obtain statistical support for project implementation. (If statistical support is requested from HTRS and the Pre-proposal is favorably reviewed, a statistical consultant will contact the applicant directly to assist in the preparation of their Full Proposal.) (See Statistical Support Requirements on page 6.)

Pre-proposal Formatting Instructions

If the applicant has questions related to the formatting instructions below, please contact HTRS at htrs@bcw.edu no later than **Friday, August 31, 2018 by 6:00 p.m. ET**, one week in advance of the Pre-proposal deadline. **Submitted Pre-proposals will be deemed ineligible if formatting instructions are not followed.**

1. Limit the Pre-proposal narrative to a maximum of three pages, excluding references.
2. Pre-proposal narrative references:
 - a. May be listed separately from the narrative but should not exceed two additional pages
 - b. Must be relevant
 - c. Must be listed in the order in which they appear in the Pre-proposal
 - d. Must list the first author and all other authors
 - e. Must have **applicant's name bolded** and mentors' names underscored

3. Use an NIH-approved font (Arial, Georgia, Helvetica, or Palatino Linotype), no less than 11 points in size, and 1-inch page margins for the Narrative and references.
4. Single or double spacing is acceptable.
5. Only generic names of products/services are allowed; names of brand names and specific companies should not be used.

Pre-proposal Review

Pre-proposals submitted on or before **Friday, September 7, 2018 by 6:00 p.m. ET** will be reviewed by the HTRS Scientific Review Committee. Although every effort is made to match reviewers' expertise to the type of proposal submitted, please prepare your Pre-proposal with the assumption that an academic or clinical hematologist may review your application (as opposed to a specialist in basic or laboratory science, for example). Any reviewer with a direct conflict of interest (such as serving as a current mentor or co-mentor to one of the applicants) 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 proposed project) is recused from reviewing the specific application in question.

The HTRS Scientific Review Committee performs the best possible Pre-proposal review based on data submitted by each applicant. The Committee's goal is to invite only the most competitive Pre-proposals to the Full Proposal round to be considered for the limited pool of MRA grant funding.

Pre-proposal Review Timeline

The HTRS Scientific Review Committee completes a thorough review of all submitted Pre-proposals. If the Pre-proposal is favorably reviewed by the Committee, the applicant will be informed within approximately two months from the Pre-proposal submission deadline (late September) that a Full Proposal is requested to allow adequate time for the Pre-proposal review process over the summer months.)

Preparing a Full Proposal

Applicants are invited to submit Full Proposals by the HTRS Scientific Review Committee as a result of successful Pre-proposal submission and review. Note that the project outlined in the Full Proposal must be substantially the same as the project described in the Pre-proposal. Invited applicants are required to follow all formatting instructions and incorporate all components of the Full Proposal (described below) into one PDF document and submit it to htrs@bcw.edu on or before **Tuesday, December 18, 2018 at 6:00 p.m. ET**.

Please note that this deadline may be readjusted due to reviewers' schedules; in this case, Full Proposal applicants will receive notification of the new due date via email.

Components of Complete Full Proposal

1. Application Form

Invited Full Proposal applicants are required to update the Application Form originally submitted with their Pre-proposal and include it as part of their Full Proposal. Applicants should be sure to update the application date on page 1 of the form before re-submitting. (If you no longer have access to your previously submitted Application Form, please request a blank form from htrs@bcw.edu.) Applications that do not include this required form will not be accepted.

2. Background and Career Goals Statement (2 pages maximum)

The Background and Career Goals Statement should address the following points and should be clear, concise and well-written. Although many of these same points were required in the Pre-proposal, it is expected that the points will be further developed for the Full Proposal as appropriate. Reviewers will use these points as guidelines to assess the quality of the applicant including a) the ability of the applicant to conduct the proposed research, and b) the potential of the applicant to build a successful career in hemostasis and/or thrombosis.

The Background and Career Goals Statement should include:

- a. Background of the applicant and preparation for the proposed research
- b. Demonstrated sincere commitment to an academic career in non-malignant hematology and/or an academic career with a major component of, or overlap with, non-malignant hematology
- c. Career development plan:
 - i. Future career goals/plans
 - ii. Relevance of the proposed research to the applicant's stated career goals
 - iii. Applicants who are not in training or 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

3. Full Proposal Narrative (10 pages maximum, excluding references)

Although every effort is made to match reviewers' expertise to the type of proposal submitted, please prepare your narrative with the assumption that an academic or clinical hematologist may review your application (as opposed to a specialist in basic or laboratory science, for example).

The 10-page Full Proposal Narrative should address the following points and be clear, concise, and well-written. Although many of these same points were required in the Pre-proposal, it is expected that the points will be further developed for the Full Proposal as appropriate. Reviewers will use these points as guidelines to assess the quality of the a) mentor(s) and environment; b) science; and c) research plan.

- a. **Quality of mentor(s) and environment** should include:
 - i. Description of the primary mentor and co-mentor's qualifications
 - ii. Quality and appropriateness of the research environment as it pertains to the applicant and project
 - iii. A clear explanation of the applicant's role vs. the role of the primary mentor and co-mentor in the research concept, design, and implementation. If relevant, specify the specific parts of the project to be carried out by the applicant as opposed to the primary mentor and co-mentor
 - iv. If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance
- b. **Quality of the science** should include:
 - i. Background, scientific merit, significance and impact of the project
 - ii. Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects
- c. **Quality of the research plan** should include clear statements of:
 - i. Hypotheses and aims/objectives of the proposed research

- ii. Study design and methodology; the project design should be appropriate to test proposed hypotheses. Project methods should support proposed aims.
- iii. Feasibility analysis
- iv. Potential limitations and how to address them
- v. Future studies to be pursued if specific aims are accomplished
- vi. Statistical plan and/or considerations. Patient or sample numbers and statistical methods should be identified. If applicable, preliminary data should be included.
- vii. Plan for obtaining statistical support. All applicants are required to identify resources for obtaining statistical support for implementing their project if selected for an MRA
- viii. Human subject or animal protections should be appropriately described, if applicable

4. A copy of the applicant's current NIH Biosketch

5. A copy of the current NIH Biosketch for the primary mentor and co-mentor (if applicable). The narrative portion of the Biosketch should describe the mentor's prior mentorship experience.

6. Letter of support from the proposed primary mentor and the co-mentor (if applicable), addressed to the HTRS Scientific Review Committee, which should include:

- a. The strengths of the applicant and any challenges that the applicant may face as an MRA Awardee
- b. The research facilities and resources available to the applicant
- c. The proportion of time the applicant will spend on research, in light of course work, clinical duties, teaching, and administrative responsibilities. (Awardees are encouraged to devote at least half of their total time to research or research-related activities, and required to devote no less than 20% of their total time to the HTRS MRA project.)
- d. A clear explanation of the applicant's role vs. the primary mentor and co-mentor's roles in the research project's concept, design, and implementation. If relevant, specify the specific parts of the project to be carried out by the applicant, as opposed to the primary mentor and co-mentor
- e. The nature of the week-to-week interactions between the applicant and the primary mentor/co-mentor. If the mentor/co-mentor are in a different institution than the applicant, an explanation of the communication plan regarding how the mentoring will be accomplished is required
- f. In what ways you have mentored and plan to mentor the applicant to improve the scientific writing of the full proposal, and future scientific writing more generally.

7. Letter of support, addressed to the HTRS Scientific Review Committee, as follows:

- a. For Fellows who will still be in Fellowship during the first and/or second year of the grant period, the letter of support should be from the fellowship program director, indicating: 1) why the applicant is an excellent candidate for an MRA; 2) that the applicant is in good standing and eligible for the award; 3) commitment of institutional support for the proposed project and 4) that 20% of the applicant's total time will be protected for the MRA while enrolled in his/her fellowship program.
- b. For current Fellows who are in their last year of fellowship at the time of this submission, two letters of support are required:
 - i. Letter of support from the fellowship program director, indicating: 1) why the applicant is an excellent candidate for an MRA; 2) that the applicant is in good standing and will complete his/her fellowship by July 1, 2019.
 - ii. Letter of support from the department chairperson or division chief, indicating: 1) why the applicant is an excellent candidate for an MRA; 2) commitment of institutional support for the proposed project and 3) agreeing that 20% of the applicant's total time will be protected for the MRA during the two-year grant period.

- c. For current Junior Attending/Junior Faculty, the letter should be from the current department chairperson or division chief, indicating: 1) why the applicant is an excellent candidate for an MRA; 2) commitment of institutional support for the proposed project and 3) agreeing that 20% of the applicant's total time will be protected for the MRA during the two-year grant period.

8. Project Budget and Addendum to Budget

The expenses below are permitted by HTRS as part of the project budget, which may not exceed (and should preferably be equal to) a total of \$162,000 USD. (Full Proposal applicants are required to use the budget template provided by HTRS .)

- a. Direct Project Costs not to exceed \$150,000 USD, including:
 - Salary and fringe benefits for the applicant proportional to his/her percent effort on the project.
 - Salary and fringe benefits for key personnel (laboratory technicians, statisticians, etc.) required to implement the research project
 - Equipment and supplies necessary to fulfill the project's specific aims
 - Registration, travel, and lodging fees for the Awardee 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 MRA-funded research. (MRA 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 Awardee'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
- b. Program Management Fees/Indirect Costs/Facilities and Administrative Costs not to exceed \$12,000 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 program management fees/ indirect costs for the entire project budget may not exceed 8% of the \$150,000 allocated to support the direct costs of the project, or \$12,000 over two years (\$6,000 per year). An applicant's two-year MRA project budget, including direct costs of \$150,000 and indirect costs up to \$12,000 may not exceed and should be as close as possible to a grand total of \$162,000 USD. Please do not add an additional \$12,000 for project management/indirect costs on top of the \$162,000 maximum, as this will exceed the amount permissible for MRA project budgets.

The applicant must provide a separate addendum to the budget template with the following information:

- a. An explanation and justification of each line item requested in the budget template.
- a. List other current and pending funding sources for the proposed project. Indicate what expenses will be covered by the additional funding and whether or not there is any overlap between the expense categories of the MRA project budget and the other funding budget(s).
- b. A brief discussion of alternatives if this additional funding is not secured.

Full Proposal Formatting Instructions

If the applicant has questions related to the formatting instructions below, please contact HTRS at htrs@bcw.edu no later than **Tuesday, December 11, 2018 by 6:00 p.m. ET**, one week in advance of the Full Proposal deadline. **Submitted Full Proposals will be deemed ineligible if instructions are not followed.**

1. Limit the Background and Careers Goals statement to a maximum of two pages.
2. Limit the Project Narrative to a maximum of ten pages, excluding references.
3. Project Narrative references:
 - a. May be listed separately from the narrative but should not exceed two additional pages
 - b. Must be relevant
 - c. Must be listed in the order in which they appear in the Full Proposal
 - d. Must list the first author and all other authors
 - e. **Must have applicant's name bolded** and mentors' names underscored
4. Use an NIH-approved font (Arial, Georgia, Helvetica, or Palatino Linotype), no less than 11 points in size, and 1-inch page margins for all documents.
5. Single or double spacing is acceptable.
6. Only generic names of products/services are allowed; names of brand names and specific companies should not be used.

Full Proposal Review Process

Invited Full Proposals submitted on or before **Tuesday, December 18, 2018 at 6:00 p.m. ET** will be reviewed by the HTRS Scientific Review Committee. Although every effort is made to match reviewers' expertise to the type of proposal submitted, please prepare your Full Proposal with the assumption that an academic or clinical hematologist may review your application (as opposed to a specialist in basic or laboratory science, for example). Any reviewer with a direct conflict of interest (such as serving as a current mentor or co-mentor to one of the applicants) 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 proposed project) is recused from reviewing the specific application in question.

The HTRS Scientific Review Committee performs the best possible Full Proposal review based on data submitted by each applicant. The Committee's goal is to select the most competitive proposals for funding. HTRS regrets that due to the limited funding available, it is not possible to award grants to all applicants. Final funding approval is granted by the HTRS Board of Directors.

Announcement of Award Recipients

The announcement of 2019 HTRS MRA award recipients will be made no later than February 2019 for grant projects beginning on July 1, 2019 and running through June 30, 2021. (The administrative program cycle for the 2019 MRA Program is July 1, 2019 through December 31, 2021.) Award funds will be disbursed within 30 days of the date of execution of the legal Grant Agreement contract between HTRS and the recipient institution.

Questions

Questions about the HTRS MRA Program should be directed to HTRS at htrs@bcw.edu or (414) 937-6569.