



**NEW AWARD:
Request for Proposals (RFP)
2022 HTRS/Spark Therapeutics Mentored Research Award (MRA)
for Gene Therapy in Hemophilia A**

- The HTRS/Spark MRA is open to MD and/or PhD applicants
- 2022 HTRS/Spark MRA Full Proposals are due **Friday, February 11, 2022 by 11:59 PM ET**
- Applications must be submitted via the HTRS online grant submission site at <https://htrs.smapply.org>.

Section 1: 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.

Section 2: About the HTRS/Spark Therapeutics Mentored Research Award (MRA) for Gene Therapy in Hemophilia A

a. Program Description

The HTRS/Spark MRA for Gene Therapy in Hemophilia A provides funding for MDs, PhDs, and/or a collaboration between two applicants (e.g. one MD and one PhD) carrying out mentored research for Gene Therapy in Hemophilia A. Fellows or junior attendings/junior faculty (MDs, PhD postdocs, DOs, MBBSs or the equivalent) pursuing careers in clinical, translational, or basic science research – specifically for Gene Therapy in Hemophilia A—are encouraged to apply.

b. Program Goals

- i. Increasing the number of skilled physician-scientists in the U.S. medical workforce dedicated to long-term research careers for Gene Therapy in Hemophilia A

- ii. Supporting innovative research by pairing talented young physician- scientists and researchers with experienced mentors, many of whom are recognized leaders in clinical and/or basic science research for Gene Therapy in Hemophilia A
- iii. Providing fellows or junior attendings/ junior faculty an accessible “on-ramp” into the NIH research pipeline by funding initial research programs that can spark and support K-award applications in these therapeutic areas

c. Project Period

The 2022 HTRS/Spark MRA project period is two (2) academic years, from July 1, 2022 through June 30, 2024.

d. Award Amount

The total grant award is \$151,800 USD. This amount includes \$151,800 to support direct expenses required to complete the proposed research (\$75,900 per year). This award pays for direct costs for the investigator’s research project only. No amount from this award can be applied to the recipient institution’s indirect costs.

e. Number and Category of Awards

HTRS has received funding from Spark Therapeutics to support one (1) 2022 HTRS/Spark Mentored Research Award for Gene Therapy in Hemophilia A. HTRS reserves the right to postpone decisions regarding the 2022 HTRS/Spark MRA Program and/or cancel the 2022 HTRS Spark MRA prior to announcing the award recipient.

Section 3: Applicant Eligibility Requirements

a. General Requirements

- i. Eligible applicants must hold a PhD, an MD, MD/PhD, DO, MBBS, or an equivalent medical degree.
- ii. Only applicants and mentors employed by academic, non-commercial institutions are eligible. Applicants must declare their intent to pursue an academic research career in hemostasis or thrombosis (or an academic research career that will have a substantial component of, or overlap with, hemostasis and/or thrombosis).
- iii. Applicants may propose collaborative research projects between two researchers (e.g. a PhD researcher and MD physician-scientist or two PhD researchers), provided the two applicants and mentor(s) fulfill eligibility criteria
- iv. Note to Canadian Applicants: Due to restrictions imposed by some pharmaceutical companies who provide grant support to support the MRA Program, HTRS may not be at liberty to fund Canadian fellows or junior attending/junior faculty for this award cycle. Interested Canadian applicants should email Jennifer Ziegler, HTRS Director of Awards Programs and Marketing, at jziegler@versiti.org to confirm eligibility prior to taking the time to submit a pre-proposal.

- v. U.S. or Canadian citizenship is not required to apply; however, award recipients must agree to live and work in the U.S. or Canada for the tenure of their HTRS/Spark MRA-funded project. J1 visa waiver applicants – even those in their first faculty positions – are encouraged to apply.
- vi. HTRS requires recipient institutions to protect no less than 20% of an awardee’s total time for the HTRS/Spark MRA Project.

b. Specific Requirements for Fellows

- i. Medical fellows must be enrolled in ACGME-accredited fellowship training programs in the U.S. (or the equivalent in Canada) to be eligible.
- ii. Postdoctoral researchers must be carrying out postdoctoral research at an academic non-commercial institution under the guidance of a mentor.
- iii. Fellows and postdocs receive free HTRS trainee membership for the duration of their training. Applicants who are fellows are required to activate their free HTRS trainee membership at www.htrs.org no later than the HTRS/Spark MRA pre-proposal deadline in order to be eligible.

c. Specific Requirements for Junior Faculty/Junior Attending

- i. Applicants with MDs (or equivalent) who have secured junior faculty/junior attending positions at U.S. or Canadian academic institutions must be within eight (8) years of completing an ACGME-accredited fellowship training program (or the equivalent in Canada) as of July 1, 2022.
- ii. Applicants with PhDs who have secured junior faculty positions at U.S. or Canadian academic institutions must be within five (5) years of completing their postdoctoral fellowship as of July 1, 2022.
- iii. For applicants who are pursuing or have completed an additional fellowship following initial training, the eight (8) year requirement is calculated from the completion date of the initial fellowship.
- iv. Junior attending/junior faculty are strongly encouraged (but not required) to become HTRS core members prior to submitting an HTRS/Spark MRA Proposal. (Membership status will not affect recipient selection.) Applicants agree to maintain active HTRS memberships for the duration of the grant period and any approved no-cost extension (NCEs) if selected as MRA recipients.

d. Qualifying Hardships

- i. HTRS will consider appeals in regard to qualifying hardships. Examples include: 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.
- ii. Potential applicants who do not meet the stated eligibility criteria but who can demonstrate qualifying hardships are encouraged to contact Jennifer Ziegler, HTRS Director of Awards

Programs and Marketing, at jziegler@versiti.org or 414-937-6562 before submitting a pre-proposal.

- iii. 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.
- iv. 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.

e. Applicants Enrolled in Higher Degree Programs

Applicants may be enrolled in a higher degree program as long as they demonstrate they have sufficient time to conduct the research project proposed in their MRA application. HTRS requires recipient institutions to protect a minimum of 20% of the awardee's total time for the HTRS MRA Project. (See Section 12a for more information regarding time commitment.)

f. Applying for More than One HTRS Award

- i. Previous HTRS MRA or THSNA MRA (Thrombosis and Hemostasis Societies of North America) recipients are not eligible to apply.
- ii. Early-stage investigators may submit separate applications to multiple HTRS award programs in the same year; however, only one HTRS award can be granted per applicant per year.

Section 4: Mentor Eligibility Requirements

a. Primary Mentors

- i. Applicants are required to select a primary mentor who is directly involved in clinical or basic science/translational science research in gene therapy or hemophilia A to be eligible for an award. Primary mentors can be MDs, DOs, MD/PhDs, PhDs, or hold an MBBS or equivalent degree.
- ii. Primary mentors are required to be active HTRS core members of record for a minimum of 12 consecutive months prior to the pre-proposal submission deadline. If the applicant's primary mentor is not a current HTRS member, or if the primary mentor joined HTRS less than 12 months prior to the deadline, the applicant must secure a co-mentor who is an active HTRS member of record and who has maintained that status for more than 12 consecutive months prior to the pre-proposal submission deadline.
- iii. If the applicant is selected as an HTRS/Spark MRA recipient, the primary mentor must maintain active HTRS membership throughout the project period and any approved NCEs.
- iv. Primary mentors must agree to supervise the applicant if an award is granted and abide by the conditions of the award throughout the project period and any approved no-cost extensions

(NCEs). They are also required to prepare a formal Letter of Support for the applicant to include in an invited full proposal application.

- v. Primary mentors are typically present at the same institution where the applicant proposes to do the majority of his/her research. However, applicants may secure a primary mentor at a different institution, as long as an effective communication plan is outlined in the pre-proposal and/or invited full proposal to indicate how mentoring will take place over distance.

b. Co-Mentors

- i. Applicants may elect to invite one or more co-mentors in addition to the primary mentor. Co-mentors should bring additional medical or scientific expertise to the project. Co-mentors can be MDs, DOs, MD/PhDs, PhDs, or hold an MBBS or equivalent degree. Applicants are not required to secure a co-mentor to be eligible for an award.
- ii. If the applicant is selected as an HTRS/Spark MRA recipient, the co-mentor (or co-mentors) must maintain active HTRS membership throughout the project period and any approved NCEs.
- iii. Co-mentors must agree to supervise the applicant if an award is granted and abide by the conditions of the award throughout the project period and any approved NCEs. They are also required to submit a formal Letter of Support for the applicant to include in an invited full proposal application.
- iv. Co-mentors are typically present at the same institution where the applicant proposes to do the majority of his/her research. However, applicants may secure a co-mentor at a different institution, as long as an effective communication plan is outlined in the pre-proposal and/or invited full proposal to indicate how mentoring will take place over distance.

Section 5: Project Eligibility Requirements

- a. Eligible research projects must exhibit a substantial component of, and relevance to, gene therapy for hemophilia A.
- b. Eligible research projects can be:
 - i. Clinical or translational science projects, including, for example, epidemiological or translational studies with or without a secondary component of laboratory work
 - ii. Basic science or laboratory projects, including, for example, molecular biology, physiology, pharmacology, biomarker, or translational studies where the primary emphasis is a laboratory component
- c. Use of the ATHNdataset or Other National Datasets. Before submitting a proposal, applicants who propose projects using the ATHNdataset or other national databases must confirm with ATHN or the owner of the database that data required for their research project are indeed contained in that database. If the proposed data are not available, the applicant should indicate that the project will be supplemented with other data and explain how and where such data will be obtained.

- d. Interested applicants should email HTRS@versiti.org prior to taking the time to submit a proposal if they have any questions regarding project eligibility.

Section 6: Distribution of Award Funds

MRAs of \$151,800 USD will be distributed by HTRS to the successful applicant's institution in three payments:

1. The first payment of \$75,900 USD (50% of the award) 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 \$60,720 USD (40% of the award) will be issued after HTRS approves a formal 12-month progress report describing research conducted during the first year of the project period.
3. The third payment of \$15,180 USD (10% of the award) is contingent upon approval by HTRS of a final, 24-month report upon completion of the project period.

Instructions for required reporting are communicated to successful applicants in their award notification letters and grant agreement contracts.

Section 7: Use of MRA Funds and Project Budget Requirements

a. General Requirements

- i. HTRS/Spark MRA funds may be used for direct costs associated with proposed research projects only. An applicant's two-year MRA project budget may not exceed a grand total of \$151,800 USD.
- ii. HTRS encourages applicants to reflect all necessary project expenses in their proposed project budgets. Any funds left unspent at the end of the project period must be returned by the recipient institution to HTRS for repayment by HTRS to the grant's pharmaceutical company supporter.
- iii. Eligible direct costs may not exceed \$151,800 USD. No amount from this award can be applied to the recipient institution's indirect costs, including grant management fees.

b. Eligible Direct Costs

- i. Awardee Stipend: Full or partial support for the awardee's salary and fringe benefits (combined as one line item). HTRS uses NIH salary caps for the awardee if applicable.
- ii. Stipends for Key Project Personnel: Full or partial support for the salaries and fringe benefits of key personnel, including laboratory technicians, statisticians, or others required to complete the project with appropriate NIH salary caps.
- iii. Equipment and supplies necessary to conduct the project

- iv. Required Travel: Conference registration fees, travel expenses, and hotel costs for the awardee to attend the HTRS Scientific Symposium or another well-recognized national or international professional meeting during the project's second year (or in the year immediately following the 24-month project period) to present his/her progress or results of MRA-funded research. MRA funds may not be used to cover registration fees, travel, or lodging expenses to attend professional meetings other than the above mentioned meeting, unless such costs are specifically approved by HTRS in advance as essential to project outcomes.
 - v. Statistical Support Costs (if provided by the recipient institution or other local resource; see also Section 10).
- c. Indirect Costs

No amount from this award can be applied to the recipient institution's indirect costs, including grant management fees or other indirect costs, including required lab or facility fees.

Section 9: Current and Pending Support Requirements

HTRS/Spark MRA applicants must report all current and pending funding sources for their proposed projects.

Applicants are encouraged to apply to their institutional Office of Sponsored Research (OSR) for supplemental funds and support. In the event that additional funding becomes available that overlaps with direct or indirect costs in the approved MRA budget, the awardee will be asked to provide a revised project budget outlining the impact of the new funds and how remaining MRA funds will be impacted or reallocated.

If the new funding covers all or substantially all of the direct and/or indirect costs previously assigned to the MRA project budget, all unused MRA funds must be returned to HTRS. More details about the impact of current and pending support on MRA award budgets are included in awardees' Grant Agreement contracts.

Section 10: Statistical Support Requirements

Statistical support is a required component of all invited MRA full proposals and MRA-funded research projects. HTRS believes that introducing early-stage physician-scientists to a structured approach to statistical planning will better prepare them to conduct their research projects successfully and go on to secure more competitive funding from the NIH or other national sources.

- a. Statistical support includes 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 identifying effective methods for analyzing data and reporting results.

Section 11: Presentation Requirement for HTRS/Spark MRA Recipients

Awardees are required to make a good faith effort to present information about their projects' research progress and outcomes at a recognized national or international professional meeting during the two-year grant period (or in the year immediately following the grant period).

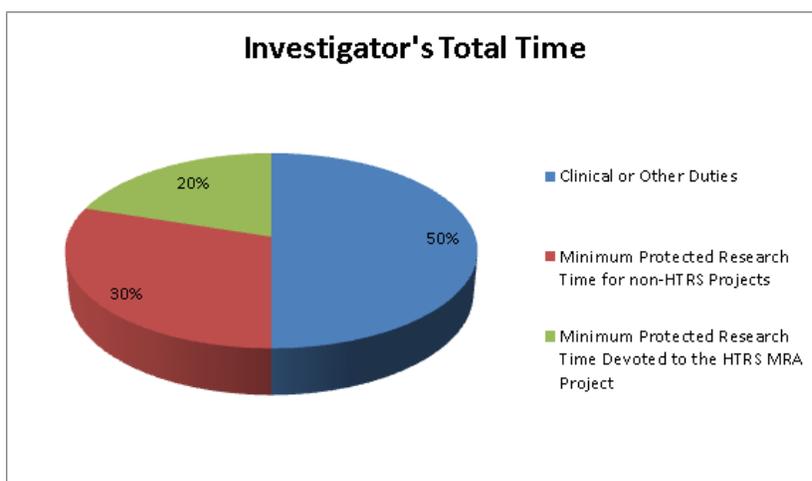
Awardees are encouraged to select the HTRS Scientific Symposium as the meeting of choice to fulfill this requirement, with the Thrombosis and Hemostasis Societies of North America (THSNA) Summit as a second choice.

Costs to support conference registration fees, travel, and lodging for this meeting must be included in the full proposal project budget. Instructions for acknowledging HTRS and the grant's commercial pharmaceutical company supporter in presentations will be included in the successful applicant's notification letter and grant agreement contract.

Section 12: Other Conditions and Responsibilities

Submission of an HTRS/Spark MRA full proposal implies acceptance of the following conditions by the applicant, the recipient institution, the primary mentor, and any co-mentors:

- a. Focus of the MRA. 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 gene therapy or hemophilia A. HTRS believes that early career awardees have an increased chance of a quality learning experience and successful project outcomes when at least 50% of their total time is protected by their institutions for research or research-related activities. HTRS encourages recipient institutions to meet this 50% level of protected time if at all possible. A minimum of 20% of the awardee's total time for the HTRS MRA Project is required by HTRS as a condition of grant acceptance.



- b. Grant Agreement Contract. Upon notification of funding, awardees are responsible for providing HTRS with the name and contact information of the appropriate financial or legal representative at their institutions who will receive the official grant agreement contract prepared by HTRS. The awardee, his/her primary mentor, any co-mentors, a representative of the recipient institution, and the HTRS Executive Director are required to sign the grant agreement before award funds can be dispersed.
- c. Change in Status. The awardee is responsible for providing HTRS with written notice of any changes 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 company or laboratory is not permitted per MRA eligibility

requirements and will result in the awardee forfeiting the MRA and the recipient returning the balance of unspent funds to HTRS. Exact conditions and instructions for submitting a change in status request are outlined in the Grant Agreement contract.

- d. Award Administration. The day-to-day administration of MRA 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 never sent to awardees directly.
- e. 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 to HTRS of Institutional Review Board (IRB) approval, along with written evidence of their institution's Federalwide Assurance (FWA) number (for U.S. investigators) and its renewal date before funding can be awarded. Written approvals must be in place for the duration of the project period in order to receive MRA funding from HTRS, and copies must be appended to the fully executed grant agreement contract. Written evidence of continuing IRB approval and FWA renewal (FWA renewal is every five years) must be submitted with each MRA progress report to confirm continued coverage.
- f. 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 to HTRS 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 before funding can be awarded. These approvals must remain in place for the duration of the project period in order to continue to receive MRA funding from HTRS. 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.
- g. Acknowledgment of HTRS and Spark Therapeutics Support. Any review articles (published or in progress), abstracts, manuscripts, or oral and poster presentations resulting from an awardee's MRA-funded research must acknowledge both the support of HTRS and Spark Therapeutics as outlined in the applicant's award notification letter and the fully executed grant agreement contract. Awardees are required to provide HTRS with copies of any articles (published and in progress), abstracts, manuscripts, or oral and poster presentations resulting from their MRA-funded research during and after the project period with appropriate acknowledgments listed.
- h. Required Reports. Award recipients are required to submit two formal reports to HTRS using the 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 (3) months of the completion of the project period. HTRS is required to share these reports with the pharmaceutical company supporter of each MRA. Awardees accept primary responsibility for understanding when reports are due and for following submission instructions provided by HTRS. Required reports 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. Complete instructions for reporting are outlined in awardees' notification letters and grant agreement contracts.

Section 13: Disclosure of HTRS Compliance with State or Federal Requirements per *Open Payments: The Physician Payments Sunshine Act*

HTRS research 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, awardees, or other particulars of funded grants with the pharmaceutical companies supporting our award programs. Such companies may, in turn, 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 pre-proposal 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 contact their institutional OSR or other grant administrator for more details, since regulations can differ by institution and state.

Section 14: Submitting the Full Proposal

a. Full Proposals

2022 HTRS/Spark MRA full proposals are due on or before **Friday, February 11, 2022 by 11:59 PM ET** and must be submitted via the HTRS SMA site at <https://htrs.smapply.org>.

Components of Complete Full Proposal

- i. **Application Form:** Applicants are required to submit through www.htrs.smapply.org online grant application site.
- ii. **Background and Career Goals Statement:** (2 pages maximum, PDF document)
The Statement should address the following points and should be clear, concise and well-written. 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 successfully career in these therapeutic areas:
 - Background of the applicant and preparation for the proposed research
 - Demonstrated sincere commitment to an academic career Gene Therapy for Hemophilia A and/or an academic career with a major component of, or overlap with, these therapeutic areas
 - Career development plan
 - Future career goals/plans
 - Relevance of the proposed research to the applicant’s stated career goals
- iii. **Full Proposal Narrative:** (10 pages maximum, excluding references)

The Full Proposal Narrative should be submitted on the HTRS online grant submission site as a PDF document.

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. Reviewers will use these points as guidelines to assess the quality of the a) mentor(s) and environment; b) science; and c) research plan

Quality of mentor(s) and environment should include:

- Description of the primary mentor and co-mentor's qualifications
- Quality and appropriateness of the research environment as it pertains to the applicant and project
- 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
- If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance

Quality of the science should include:

- Background, scientific merit, significance and impact of the project
- Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects

Quality of the research plan should include clear statements of:

- Hypotheses and aims/objectives of the proposed research
- Study design and methodology; the project design should be appropriate to test proposed hypotheses. Project methods should support proposed aims.
- Feasibility analysis
- Potential limitations and how to address them
- Future studies to be pursued if specific aims are accomplished
- Statistical plan and/or considerations. Patient or sample numbers and statistical methods should be identified. If applicable, preliminary data should be included.
- 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
- Human subject or animal protections should be appropriately described, if applicable
- For co-applicants submitting a collaborative proposal, a clear explanation of each applicants' role in the research

- iv. **A copy of the applicant's (or applicants') current NIH Biosketch(es)** (submitted online as a PDF document)
- v. **A copy of the current NIH Biosketch for the primary mentor and co-mentor(s)** (if applicable). (Submitted online as a PDF document) The narrative portion of the Biosketch should describe the mentor's and co-mentor's prior mentorship experience.
- vi. **Letter of support from the proposed primary mentor and the co-mentor(s) (if applicable)**, (submitted online as PDF documents) addressed to the HTRS Scientific Review Committee, which should include:
 - The strengths of the applicant and any challenges that the applicant may face as an MRA Awardee

- How the applicant will advance the HTRS mission and the field of benign hematology
- The research facilities and resources available to the applicant
- 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.)
- 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
- 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
- In what ways the mentor/co-mentor has mentored and plans to mentor the applicant to improve the scientific writing of the full proposal, and future scientific writing more generally
- Primary mentors and/or co-mentors who have been ongoing HTRS members should express their prior involvement and commitment to HTRS, its mission, and the field of benign hematology
- Primary mentors who have not been HTRS members in the past should provide justification for their role

vii. **Letter(s) of support**, (submitted online as PDF documents) addressed to the HTRS Scientific Review Committee, as follows:

- For Medical 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.
- For current Medical Fellows who are in their last year of fellowship at the time of this submission, two letters of support are required: 1) Letter of support from the fellowship program director, indicating why the applicant is an excellent candidate for an MRA; and that the applicant is in good standing and will complete his/her fellowship by July 1, 2022. 2) Letter of support from the department chairperson or division chief, indicating why the applicant is an excellent candidate for an MRA; commitment of institutional support for the proposed project; and agreeing that 20% of the applicant's total time will be protected for the MRA during the two-year grant period.
- For current postdocs and junior attending/junior faculty applicants, 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.

viii. **Project Budget** (submitted online as one PDF document)

The expenses below are permitted by HTRS as part of the project budget, which may not exceed a total of \$151,800 USD. It is in the awardee's best interest if the budget total expenses are as close as possible to \$151,800 USD so that the total grant award is used.

Applicants are required to use the budget template provided by HTRS. Direct Project Costs not to exceed \$151,800 USD, including but not limited to:

- 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

No amount from this grant can be applied to recipient institution's indirect costs, including: Lab fees, facility fees, or other costs related to the management of the funded research program by the recipient institution.

ix. **Addendum to Budget** (submitted online as one PDF document)

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

- An explanation and justification of each line item requested in the budget template.
- Other current and pending funding sources for the proposed project, if they exist. If so, 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).
- A brief discussion of alternatives if this additional funding is not secured.

If the applicant has questions related to the info below, please contact HTRS at HTRS@versiti.org no later than **Friday, January 14, 2022 by 11:59 p.m. ET**. These guidelines **MUST** be followed:

- Limit the Background and Careers Goals Statement to a maximum of two pages.
- Limit the Project Narrative to a maximum of 10 pages, excluding references.
- Project Narrative references:

- May be listed separately from the narrative but should not exceed two additional pages
- Must be relevant
- Must list the first author and all other authors
- **Must have applicant's name bolded** and mentors' names underscored.
- Only generic names of products/services are allowed; names of brand names and specific companies should not be used

c. Proposal Review

The HTRS Scientific Review Committee performs the best possible reviews based on data submitted by each applicant.

Every effort is made to match reviewers' expertise to the proposals submitted. 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.

Section 15: Notification and Announcement of Award Recipients

Individual award notifications and the official announcement of all 2022 HTRS/Spark MRA for Gene Therapy in Hemophilia A recipients will be made no later than April 2022 for projects beginning on July 1, 2022 and extending through June 30, 2024.

HTRS will make every effort to disperse HTRS/Spark MRA funds for approved projects 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/Spark MRA Program for Gene Therapy in Hemophilia A or applying for an MRA should be directed to Jennifer Ziegler at jziegler@versiti.org, or at HTRS@versiti.org.