

# Request for Applications (RFA) Hemostasis and Thrombosis Research Society (HTRS) 2024 HTRS/Novo Nordisk Clinical Scholar Award in Hemophilia and Rare Bleeding Disorders

# 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 <a href="https://www.htrs.org">www.htrs.org</a>.

# Section 2: About HTRS/Novo Nordisk Clinical Scholar Award Program

# a. **Program Description**

The HTRS and Novo Nordisk Inc. (Novo) announce the availability of one Clinical Scholar Award (CSA) focused on Hemophilia and Rare Bleeding Disorders for one academic year – July 1, 2024 to June 30, 2025.

The 2024 CSA is supported by an educational grant to HTRS from Novo. During the clinical scholar year, the 2024 CSA recipient is mentored by an experienced MD, MD/PhD, or DO working in hemophilia and rare bleeding disorders at an established U.S.-based hemostasis treatment center (HTC), hospital, or university.

Applicants must present an education plan for the CSA year to obtain expertise in the clinical care of patients with hemophilia and rare bleeding disorders. It is strongly encouraged to include a scholarly activity as part of the CSA plan. A scholarly activity may include participation in the mentor's clinical research, helping to develop a clinical or educational program, a quality improvement project, or committing to specific additional educational activities/coursework intended to advance a career in hemostasis clinical care or research.

#### b. **Program Goals**

 Provide financial support for an early-career physician interested in enhancing his/her clinical training in hemostasis by engaging in a 12-month, intensive clinical scholar year focused on Hemophilia and Rare Bleeding Disorders under the guidance of an experienced mentor ii. Combat the shortage of skilled benign hematologists in the U.S. by providing funding, mentorship, and career development support to an early-career physician pursuing this career path

#### c. **Project Period**

The 2024 CSA grant period is one (1) academic year, from July 1, 2024 through June 30, 2025.

#### d. **Award Amount**

The maximum grant is \$119,600 USD, including an \$80,000 stipend for the award recipient and a \$39,600 stipend for the primary mentor at the U.S.-based HTC, hospital or university identified in the applicant's proposal.

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, students 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 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.

# **Section 3: Applicant Eligibility Requirements**

- a. General Requirements:
- i. Eligible applicants must be U.S.-based MDs or DOs in pediatric or adult medicine
- ii. Applicants must have completed the first two years of fellowship in an accredited U.S. Hematology, Hematology/Oncology, or Pediatric Hematology/Oncology training program. Applicants currently in training are encouraged to apply if they anticipate completing fellowship by July 1, 2024.
- iii. Applicants up to five (5) years post-fellowship as of July 1, 2024 are eligible to apply. Individuals who have already achieved the rank of Associate Professor or who have held faculty positions for longer than five (5) years post-fellowship, are *not* eligible to apply.
- iv. **Applicants must identify a mentor** who is an experienced academic physician or physician-scientist (MD, MD/PhD, or DO) working in Hemophilia and Rare Bleeding Disorders at a U.S.-based HTC, hospital, or university. *Mentors cannot be HTRS industry members*.
- v. **Applicants may identify a co-mentor** if training opportunities during the scholar year would be enhanced by the participation of a co-mentor. Either the applicant's primary mentor <u>OR</u> co-mentor is <u>required to be an</u> HTRS Core member prior to the CSA application submission deadline.

- vi. **Both the mentor, co-mentor (if applicable), and the recipient institution must agree to host** and supervise the CSA award recipient by signing a legal Grant Agreement to be prepared by HTRS prior to the start of the CSA grant period.
  - vii. **HTRS Membership Requirements:** Applicants still in fellowship must activate their free HTRS Trainee Memberships prior to the CSA application deadline at <a href="www.htrs.org">www.htrs.org</a>. Junior Faculty hematologists who are not currently HTRS members, if selected to receive a 2024 CSA, must sign up for HTRS Core Membership as a condition of their award acceptance prior to signing the formal Grant Agreement. For CSA recipients, either the mentor or co-mentor is encouraged to maintain HTRS Core membership for the duration of the grant period including during an approved no-cost extension.

viii. Previous HTRS Mentored Research Award or HTRS/ATHN DREAM Award recipients may apply for the CSA if the clinical scholar period does not overlap with either of these award periods. Previous HTRS/Novo Nordisk CSA recipients are *not* eligible to apply. Applicants generally may *not receive* more than one HTRS award with overlapping grant periods in a given year. Applicants applying in the same year for both the CSA and another HTRS award should contact HTRS at <a href="mailto:jziegler@htrs.org">jziegler@htrs.org</a> to discuss eligibility before preparing a CSA application.

# Section 4: Available Funding and Use of Funds

#### a. <u>Support from Novo:</u>

The 2024 CSA Program is supported by a medical educational grant to HTRS from Novo Nordisk Inc. The maximum CSA is \$119,600 USD, which includes an \$80,000 stipend to support the recipient's clinical training in Hemophilia and Rare Bleeding Disorders for one year, and \$39,600 honoraria for the applicant's primary mentor and/or co-mentor to be shared according to the individual mentors and/or institution's agreed-upon stipulations. CSA funds support only these expenses and cannot be used for any other direct or indirect costs associated with the scholar year without prior written permission from HTRS. If presenting a case for other direct or indirect costs, a budget must be provided within the narrative section of the application.

#### b. Funding Distribution:

The maximum amount of \$119,600 USD will be distributed by HTRS to the recipient institution in three payments:

- i. The first payment of \$59,800 USD (50%) will be issued after full execution of the legal Grant Agreement contract between HTRS, the awardee, and the recipient institution.
- ii. The second payment of \$47,840 USD (40%) will be issued after acceptance by HTRS of a formal six-month *Progress Report* describing the awardee's progress toward achieving the goals and objectives outlined in the CSA application.
- iii. The third payment of \$11,960 USD (10%) is contingent upon acceptance by HTRS of a *Final Report* summarizing the completed 12-month scholarship period.

Instructions about required reports are communicated to the successful applicant in the CSA notification letter and Grant Agreement contract.

### **Section 5: Mentor Eligibility Requirements**

#### a. Primary Mentors

- i. Applicants are required to select a primary mentor who is directly involved in clinical research in classical hematology to be eligible for an award. Primary mentors can be MDs, MD/PhDs, DOs, or hold an MBBS or equivalent degree.
- ii. If applicants are interested in applying for the HTRS CSA Program but do not have a mentor, HTRS may be able to help identify one. Applicants looking for a mentor should email <a href="mailto:jziegler@htrs.org">jziegler@htrs.org</a>, and HTRS will help match the applicant with an appropriate mentor.
- iii. Primary mentors are required to be active HTRS core members of record for a minimum of 12 consecutive months prior to the 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 comentor 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.
- iv. If the applicant is selected as a CSA recipient, the primary mentor must maintain active HTRS membership throughout the project period and any approved NCEs.
- v. 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 the application.
- vi. 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, 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 a CSA 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 6: Preparing a 2024 CSA Proposal

- a. <u>Guidelines</u>
- i. To apply for a 2024 CSA, applicants must submit a complete proposal to HTRS via our online grant submission site at <a href="https://htrs.smapply.org">https://htrs.smapply.org</a> by Friday, January 26, 2024 at 11:59 p.m. ET. The system will confirm receipt via email. If you submit an application but do not receive a confirmation email within 72 <a href="https://hours.please.contact.jziegler@htrs.org">hours.please.contact.jziegler@htrs.org</a> for confirmation of receipt. The site allows you to save your application to complete at a later date.
- b. <u>Components of a Complete CSA Proposal</u>
- i. **Application Form:** Applicants are required to complete the Application Form within the HTRS online grant submission site.
- ii. **Applicant Narrative** (5 pages maximum, excluding references): The CSA Narrative should be uploaded to the HTRS online grant submission site as a PDF. The elements of a complete CSA narrative include:
  - iii. A statement of commitment to a career in Hemophilia and Rare Bleeding Disorders, including future career plans
  - iv. A description of the applicant's background and preparation for a career in Hemophilia and Rare Bleeding Disorders Education plan to obtain expertise in the clinical care of patients with Hemophilia and Rare Bleeding Disorders. Applicants are strongly encouraged to include a scholarly activity in their goals that goes beyond the clinical care of patients (e.g., assisting in a mentor's clinical research, helping to develop a program, or committing to additional education meant to advance a career in hemostasis clinical care or research, such as quality improvement).

Please include a statement recognizing the following minimum requirements for clinical time during the scholar year:

- 1. Longitudinal outpatient clinic experience with a focus on diagnosing and management of patients with bleeding disorder for at least 1 half-day each week
- 2. Observation in the clinical coagulation laboratory either as at least a 2-week block experience or a longitudinal 4-8 hours/month experience with emphasis on learning the details of coagulation assays (PT, PTT, factor levels) and platelet function assays (PFA-100, platelet aggregation)
- iii. Persuasive Statement explaining why the applicant is the best choice to receive a CSA
- iv. **Salary Support**: Applicants must report all current and pending sources of salary support in the CSA proposal narrative for the July 1, 2024 to June 30, 2025 academic year. In the event that additional funding becomes available to cover salary support, the award recipient will be asked to provide documentation to HTRS that expenses supported by the 2024 CSA Program do not overlap with the new funding. If the new funding negates the need for stipend support for the recipient and the mentor, any remaining 2024 CSA grant funds being held in reserve by the recipient institution must be returned to HTRS.
- v. **Applicant's CV or current NIH Biosketch** (submitted online as a PDF)

- vi. **Proposed mentor's and co-mentor's (if applicable) current NIH Biosketch** (submitted online as a PDF). The narrative portion of the Biosketch should describe the mentor's prior mentorship experience
- vii. Letters of Support (submitted online as a PDF):
  - 1. Letter(s) of Support from the Proposed Mentor (and Co-Mentor, if applicable), including confirmation of the mentor's willingness to work with the applicant at specified institution
  - 2. Letter of Support from the applicant's Clinical Supervisor (Fellowship Program Director if fellow; Department/Division Chief if faculty)
  - 3. If the applicant is enrolled in a fellowship program at the time of application, letter of support from the applicant's current Fellowship Program Director is required, including a statement confirming the applicant is in good standing and will complete the fellowship by July 1, 2024, and the intention to pursue a career in hemostasis.
  - 4. If the applicant is faculty, Letter of Support from applicant's current department/division chief, confirming the applicant is in good standing and applicant's intention to pursue a career in hemostasis.

#### SECTION 7: Peer Review Criteria - How Proposals will be Evaluated

- a. <u>Categories for reviewer scoring:</u>
- i. Quality of Proposed Mentor/s and HTC Environment
- Scoring Range: 0-10
- ii. Commitment of Mentor/s to Support Applicant During the Scholar Year
  - Scoring Range: 0-10
- iii. Applicant's Qualifications, Background, and Preparation for Scholar Year
  - Scoring Range: 0-15
- iv. Career Goals, including Relevance and Potential Impact of CSA to Stated Career Goals
  - Scoring Range: 0-10
- v. Goal(s) for the Scholar Year and Specific Objectives/Aims Necessary to Achieve Goals
  - Scoring Range: 0-10
- vi. Sincere Commitment to Career in Hemophilia/Rare Bleeding Disorders
  - Scoring Range: 0-15
- vii. Persuasive Statement: Explanation of Why Applicant is the Best Choice for the Award
  - Scoring Range: 0-10
- viii. Overall Impact and Potential of Application
  - Scoring Range: 0-20

# a. <u>Special Considerations</u>:

- i. Do the goals include a scholarly activity that goes beyond the clinical care of patients (such as assistant in a mentor's clinical research, helping to develop a program, or committing to additional education meant to advance a career in hemostasis clinical care or research, such as quality improvement?
- ii. Did the applicant include a scholarly activity in the plan for the fellowship year?
- iii.Inclusion of a scholarly activity in the plan for the fellowship year is not a requirement of the CSA Program; however, evidence of scholarly activity will strengthen the application and be viewed by the HTRS CSA Review Committee as further evidence of the applicant's dedication to building a career in hemostasis.

#### **SECTION 8: Application Review Process**

#### a. <u>Review Committee</u>:

Proposals submitted by **Friday**, **January 26**, **2024** at **11:59** p.m. **ET** will be reviewed by members of the HTRS CSA Review Committee, a peer review committee of HTRS member physicians. Any reviewer with a direct conflict of interest (such as a close personal or professional relationship with any applicant) is recused from reviewing the specific application in question.

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

## **SECTION 9: Conditions and Responsibilities**

- a. Submission of a CSA proposal implies acceptance of the following conditions by the applicant, the recipient institution, and the mentor or co-mentor:
- i. Required Grant Agreement. Upon notification of an award, the CSA recipient is 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 award recipient, the mentor and/or co-mentor, the recipient institution's representative, and the HTRS Executive Director or other HTRS Board members are required to sign a Grant Agreement contract prepared by HTRS before award funds can be dispersed.
- ii. <u>Change in Status</u>. The award recipient is responsible for providing HTRS with written notice of any Change in Status related to their clinical scholar year or career path at any time during the grant period. Change in Status notification letters are subject to review and approval by HTRS. While most requests for Change in Status are negotiable, it should be noted that a change in career direction from an academic institution to commercial industry, for example, is not permitted per CSA eligibility requirements and will result in the award recipient returning the balance of the CSA funding to HTRS. Exact conditions and instructions for submitting a Change in Status request are outlined in the Grant Agreement contract.

- iii. <u>Award Administration</u>. The day-to-day administration of award funds is the responsibility of the recipient institution. As such, the recipient institution issues award funds as outlined in the approved project budget \$80,000 for the awardee's stipend and \$39,600 for the mentor's honoraria, as outlined above according to its own procedures and payment schedules. Funds are not sent to award recipients directly.
- iv. Articles, Abstracts, and Oral/Poster Presentations and Acknowledgements. Any articles (published and in progress), abstracts, or oral and poster presentations resulting from the CSA must acknowledge the support of both HTRS and Novo Nordisk Inc. as outlined in the applicant's award notification letter and the fully executed Grant Agreement contract. After the grant period, the awardee is required to provide HTRS with a final published copy of any articles, abstracts, or oral and poster presentations resulting from his/her scholar year that includes appropriate acknowledgement of award support.
- v. Required Reports. The awardee is required to submit two formal reports via the HTRS grant system: 1) a Progress Report after the first six months of the clinical scholar period, and 2) a Final Report within three months of the completion of the award period. HTRS is required to share these reports with Novo. As such, the awardee should prepare his/her report to include supporter acknowledgment as outlined in his/her Grant Agreement contract. Required reports must also include a list of any articles (published and in progress), abstracts, or oral and poster presentations resulting from the CSA-funded scholar year, 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.
- vi. <u>Progress Report</u>: This report is a narrative of progress made during the first six months of the clinical scholar year. The report must be submitted via the HTRS grant system. The second payment of the Grant is contingent upon satisfactory progress having been made during the first six months, as determined by HTRS, per the goals and objectives outlined in the original CSA application. 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 for the scholar year is not made available.
- vii. Final Report: This report consists of two parts: a narrative report on progress made over the entire award period and a financial report outlining expenses incurred during the entire award period. Both reports must be submitted via the HTRS online grant system. The third and final payment of the Grant is contingent upon:

  1) satisfactory progress having been made during the tenure of the award as determined by HTRS, per the goals and objectives outlined in the original application; and 2) acceptance by HTRS of expenses submitted by the recipient institution, as compared to the most current, approved version of the clinical scholar 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 is not made available.

# **SECTION 10: Announcement of Award Recipients**

# a. March 2024:

The announcement of the 2024 HTRS/Novo Nordisk CSA award recipient will be made no later than early March 2024 for the grant period beginning on July 1, 2024, and running through June 30, 2025. 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.

#### **SECTION 11: Past Recipients Share Value of Program**

#### a. Testimonials:

To reflect the value of this experience, the following testimonials attest to the positive outcomes gained as reported by these past HTRS-member CSA recipients:

# • Holleh D. Husseinzadeh, MD, MSCE, 2016 Award Recipient (formerly named Clinical Fellowship)

"During my HTRS/Novo Nordisk Clinical Fellowship, I grew tremendously as a clinician and subspecialist within the non-malignant hematology specialty. I believe this experience is largely responsible for the attainment of my current position as Assistant Professor at Thomas Jefferson University Hospitals. I would like to wholeheartedly thank HTRS and Novo Nordisk for the honor of this fellowship."

#### • Tiffany F. Lucas, MD, 2016 Award Recipient

"The HTRS/Novo Nordisk Clinical Fellowship allowed me not only to develop clinical expertise in pediatric bleeding disorders care but also to develop skills in quality improvement and medical education that I am continuing to apply to my scholarly pursuit as an early academician. Ensuring that there is a mentor who can guide the fellow during this time is critical to introducing hemostasis thrombosis topics, which often is a neglected portion of hematology/oncology fellowship. In addition, research mentorship is key to starting research in hemostasis thrombosis. Thank you for your ongoing support of young investigators in the field of non-malignant hematology!"

\*Pediatric hematology/oncology fellowship program director at UCSF Benioff Children's Hospital San Francisco. In addition, received the Clinician Educator Award from American Society of Pediatric Hematology/Oncology and awarded by the American Society of Hematology for the Medical Educator's Initiative.

### • Beth Warren, MD, 2015 Award Recipient

"The HTRS CSA allowed me to have protected research time following my peds hem/onc fellowship – this award launched my clinical research career. While my fellowship research project had been in lab research, as time progressed, I suspected that I would be a better match for clinical research, and this ended up being true! The HTRS CSA allowed me protected time to analyze a project previously started by my mentor. I was able to enroll in a Master of Science of clinical science program at the same time and use the statistics skills I was learning directly on the project, which really cemented those skills. The results led to exploring other possible modifiers of joint outcomes, which led to a K23 grant application that has recently been favorably scored. The mentorship was completely critical. I would have floundered more if not for my mentor, who helped me realize that research and patient care are very intertwined, and that I didn't have to choose between them.

\*Assistant Professor, University of Colorado Anschutz Medical Campus

# **SECTION 12: Disclosure of HTRS Compliance with State or Federal Requirements**

The HTRS/Novo Nordisk Clinical Scholar Award 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 the CSA recipient institution, awardee, mentor or co-mentor, or other particulars of this program with Novo Nordisk Inc.

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

#### Questions

Questions about the 2024 HTRS/Novo Nordisk Clinical Scholar Award in Hemophilia and Rare Bleeding Disorders should be directed to HTRS at <u>jziegler@htrs.org</u>.

HTRS is grateful for educational grant support from **Novo Nordisk Inc.** for this clinical scholar program.