



CARE Award Request for Proposals The American Thrombosis and Hemostasis Network (ATHN)

The CARE Award is designed to:

- **Advance knowledge** in hemostasis by funding investigator-initiated research or to test quality metrics and intervention strategies conducted by nurses and other members of the interdisciplinary team under the guidance of experienced mentors
- **Transform the care of patients** with bleeding and clotting disorders through the use of the national ATHNdataset
- **Provide career enrichment** for nurses and other members of the interdisciplinary HTC team dedicated to the field of hemostasis disorders

Award Summary

- Eligible applicants for this research award, which utilizes data from the ATHNdataset, are nurses and other members of the interdisciplinary team at ATHN-affiliated HTCs
- The award offers funding up to \$50,000 per recipient for projects lasting up to one year
- Contact support@athn.org for credentials to log into the online application to submit your pre-proposal on or before February 28, 2018
- Selected applicants will be invited to submit full proposals and will be notified in March 2019
- Invited full proposals are due on or before May 31, 2019
- Awards will be announced in June 2019
- Award recipients are expected to present a poster at the ATHN Data Summit 2020

ATHN is grateful to Novo Nordisk for making this award possible through a medical education grant.

1. Overview

The American Thrombosis and Hemostasis Network (ATHN) is a non-profit, 501(c) 3 corporation founded in July 2006. ATHN's vision is to advance and improve the care of individuals affected by bleeding and thrombotic disorders. ATHN provides stewardship of a secure national database infrastructure, adherent to all privacy guidelines, which will be used to support clinical care and outcomes analysis, research, advocacy, and public health reporting in the hemostasis and thrombosis community.

The ATHNdataset now contains demographic and clinical information on over 38,000 patients including over 12,000 with factor VIII (FVIII) deficiency, over 3,5000 with factor IX (FIX) deficiency and over 2,000 with rare factor disorders. As a patient-centric, disease-based longitudinal registry of standardized data, the ATHNdataset can now be used to answer research questions and to assess quality of care.

ATHN is seeking proposals for the next round of CARE Awards that support and mentor nurses and other members of the interdisciplinary team in the use of the ATHNdataset for research. Nurses and other members of the interdisciplinary teams at HTCs across the U.S. have research interests that could be informed by real-life data about the patients with bleeding and clotting disorders they serve, including patients with hemophilia A and B, von Willebrand disease, and rare bleeding disorders. These data include longitudinal patient-level data regarding disease severity, inhibitor status, episodic and

prophylaxis treatment strategies, current treatment regimens, co-morbidities, payers, and demographics.

2. The ATHNdataset

The ATHNdataset is a powerful dataset that might be used as a starting point to answer research questions. Previously funded CARE Award projects included research focused on:

- The effect of socioeconomic status and urbanization on rates of self-infusion & bleed rate in adolescents with severe hemophilia
- Opioid use in hemophilia

3. Award Program Description

This CARE Award will provide financial support for nurses and other members of the interdisciplinary team at ATHN-affiliated HTC, enabling them to conduct research using the ATHNdataset under the guidance of an experienced mentor. Projects eligible for this award are expected to be approximately 12 months in duration.

3.1 Eligibility

Eligible proposals will utilize data from the existing ATHNdataset. Proposals might include longitudinal, case/control, feasibility, development and testing of quality metrics and interventions, comparative-effectiveness, or cost-effectiveness initiatives. Measurable objectives to be reached by the end of the grant period and a timeline will be required in all applications. The specific data elements of the ATHNdataset that will be evaluated in the proposed study should be identified from the ATHNdataset core data elements and specified in all applications.

Applicants must be a nurse, advanced practice provider, social worker, physical therapist, genetic counselor or other member of the interdisciplinary team at an ATHN-affiliated HTC. The applicant's HTC must be an ATHN Affiliate in good standing, enrolling patients in the ATHNdataset at the time of application.

Mentors must be established clinicians, epidemiologists, or related researchers working in an ATHN-affiliate HTC. Mentors must agree to provide guidance to the applicant in the proposed research at his/her ATHN-affiliated HTC. Mentors must also be familiar with both the goals of the applicant's proposed research and the mentoring requirements of the award. It is preferable to have a mentor who is experienced in conducting data set research as well. A formal letter of support will be required from the mentor.

3.2 Application Submission and Selection

The ATHN CARE Award is a competitive award and an ATHN Research Review panel reviews all applications. The pre-proposal process is used to assess response to eligibility requirements, technical feasibility, and scientific integrity. Full proposals will be invited for submission.

Pre-Proposals are due on or before February 28, 2019. Proposals will be submitted through ATHN's online application process. Contact support@athn.org to request a link to the application. Pre-proposals will require the following components:

- The completed online application

- A research concept that includes scientific background and rationale, main hypothesis and proposed research aims, characteristics of the study population, ATHNdataset core data elements of interest, methodology including statistical approach (not to exceed 2 pages)
- Name of mentor and their institution/ATHN-affiliated HTC
- Brief description of mentor qualifications and role in the project
- If proposal includes information that is not included in the ATHNdataset core data elements, specification of these data elements to be extracted from medical records should be included.
- Lay abstract/project description (100 words)

Notifications to submit a full proposal will go out in March 2019. Invited proposals will be due on or before May 31, 2019 and include the following components:

- The completed award application
- A research plan that includes scientific background and rationale, main hypothesis and proposed research aims, characteristics of the study population, ATHNdataset core data elements of interest, methodology including statistical approach, and timeline (not to exceed 5 pages)
- A brief description of mentor qualifications and role in the project
- References
- Biosketch
- Description of the applicant's research resources and environment
- Project budget
- Letters of support (required from HTC Director and mentor; others are optional)

3.3 Selection of Recipients

Applications will be reviewed and scored by an ATHN Research Review panel. Any reviewer with a direct conflict of interest (such as being a current mentor to an applicant) is recused from the entire review process. Any reviewer with an indirect conflict of interest (such as a close professional relationship with any applicant, or previous involvement in applicant's proposed project) is recused from reviewing the specific application in question.

CARE Award applications will be judged according to the following criteria:

- Scientific merit of proposal
 - Relevance and timeliness of research question
 - Potential for research to contribute new knowledge in the field of hemostasis
 - Availability of data in ATHNdataset
 - Clarity of plan to utilize ATHNdataset
- Overall quality of application
 - Response to all application components (listed above in Section 3.2)
 - Realistic timeline and feasibility of completion during award period
 - Appropriate statistical support plan

ATHN will reserve the right to determine the number and category of awards granted through the CARE Award based on the quality of submitted proposals, the availability of grant funding to ATHN, or other restrictions imposed by educational grant sponsors.

3.3 Award Recipient Use of Funds

CARE Award funding may be applied to the applicant's salary and fringe benefits (commensurate with

academic rank at their appointing institution) and/or to other direct project costs. Other direct costs might include data extraction and validation and statistical services from ATHN for the proposed project. (See section 4. ATHN Technical Assistance below.) The maximum grant for a project will be \$50,000.

If indirect costs (institutional overhead or hospital/research facility fees) are requested by the applicant's HTC as part of the project budget, the indirect costs may not exceed 10% of the total project budget, or cause the total project budget to exceed \$50,000.

Up to \$1,500 of the direct costs of the project budget may be used to support the recipient's travel to the ATHN Data Summit or other relevant national scientific meetings to present findings of the funded research. (Funds may be used to cover registration, travel, or lodging expenses to attend professional meetings with direct relevance to the research.)

Funding will be distributed in two payments, with the first payment paid within 30 days of the signing of the contract and the second paid at the conclusion of the project. Final payment is contingent upon submission and successful review of a required Final Report.

3.4 Grant Administration by Award Recipient

Prior to initiating a project and throughout the project period, the award recipient will be expected to meet certain administrative requirements.

IRB Review and Approval is not required as the recipient will use and validate the ATHN dataset, a HIPAA-compliant, non-identifiable limited data set, consistent with the patient authorizations executed by participating patients. **Administration of Funds** will be through the awardee's institution. Funds will not be sent to awardees directly. HTCs are responsible for using award funds to cover expenses outlined in approved project budgets according to their own procedures and payment schedules.

Grant Agreement prepared by ATHN will be executed by the awardee, his/her mentor, a legal representative of the applicant's institution, and an ATHN representative upon acceptance of the CARE Award and before award funds will be released. The recipient will use best efforts to execute Grant Agreement within two (2) months of receipt. A standard ATHN Researcher Data Sharing Agreement will also be required.

Acknowledgment of Support in any publication, thesis, or presentation reporting the results and/or analyses of the research funded by this award shall include an acknowledgement of the support of the American Thrombosis and Hemostasis Network (ATHN) and Novo Nordisk as the industry sponsor supporting the award, and include appropriate attribution for the ATHN dataset and ATHN-affiliated HTCs. Awardees must submit all draft publications to ATHN for review prior to submission and agree to provide ATHN with a copy of publication, poster, and/or presentation if published and reporting the results and/or analyses of funded research during and after the duration of the award program period.

A Final Report to ATHN that includes a narrative summary, list of publications, and a financial report will be required from all recipients within three (3) months of the end of the final award year. A brief 6-month Status Report is also required.

4. ATHN Technical Assistance

To adequately assist applicants and award winners in the competitive application process and in implementing the award, ATHN will provide technical assistance and grant management services.

Access to the ATHNdataset Core Data Elements is available at athn.org in order that applicants can become familiar with the type of data available, and therefore the types of projects that could be supported by the ATHNdataset.

Applicants are encouraged to meet with a designated ATHN Administrator at their ATHN-affiliated HTC to better understand the data collected using the ATHN Clinical Manager.

An informational webinar will be conducted in January 2019 on a date to be announced. The webinar will provide assistance to prospective applicants in designing research projects that apply the ATHNdataset to their research questions and to answer questions about the ATHNdataset. All applicants are encouraged to attend the webinar, which will also review the program announcement and submission guidelines. Applicants may also request statistical support from ATHN to develop their research project study design. Discussions with the ATHN biostatistician and preliminary data queries are encouraged to help determine feasibility of a study and refine a potential research question. For the actual project, use of ATHN's biostatistician is at a fee-for-service basis and can be arranged as part of the project. In the proposal, the rationale for statistical support should be clearly outlined and may be supported by award funding if this is of benefit to the applicant and the project.

5. Award Program Timeline

Milestone	Date
Deadline for Pre-Proposals	February 28, 2019
Invitation for Full Proposals	March 2019
Full Proposals Due	May 31, 2019
Award Recipients Announced	June 2019
Final Reports Due	June 2020
Poster or Presentation at Data Summit 2020	2020

Questions?

Questions about the CARE Award, including requests for credentials to apply and submit a Pre-Proposal through the required online submission process should be sent to support@athn.org.