



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 non-physician 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 March 3, 2020.
- Selected applicants will be invited to submit full proposals and will be notified in April 2020
- Invited full proposals are due on or before June 10, 2020
- Awards will be announced in August 2020
- Award recipients are expected to submit an abstract during the ATHN Data Summit call for abstracts period and if accepted, present a poster at the ATHN Data Summit 2021

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 blood disorders. ATHN provides stewardship of a secure national 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 blood disorders community.

The ATHNdataset now contains demographic and clinical information on over 41,372 patients including 13,324 with factor VIII (FVIII) deficiency, 3,970 with factor IX (FIX) deficiency and 2,343 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. Non-physician HTC team members from 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
- Is Aging Out of Medicaid Associated with Change in Treatment Patterns Among Young Adults?

3. Award Program Description

This CARE Award will provide financial support for non-physician 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, 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-affiliated 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. 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 review panel will review 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.

Before Submitting a Pre-proposal

1. Applicants are expected to review the ATHNdataset Core Data Elements on the last page of this RFP prior to submission in order to become familiar with the type of data available (and therefore the types of projects that could be supported by the ATHNdataset).

2. Applicants are encouraged to meet with the ATHN Administrator at their site to better understand the data collected using the ATHN Clinical Manager. Applicants are encouraged to review the ATHN Research Report Brief available in Clinical Manager to become more familiar with the data elements available in the ATHNdataset.

Pre-Proposals are due on or before March 3, 2020. 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
- Lay abstract/project description (100 words)

Notifications to submit a full proposal will go out in April 2020. Invited proposals will be due on or before June 10, 2020 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 review panel. 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 blood disorders
 - 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 reserves the right to determine the number and category of awards granted through the CARE Award based on the quality of submitted proposals and the availability of grant funding to ATHN.

3.4 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 to present findings of the funded research. (Funds may be used to cover airfare and lodging expenses.)

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

3.5 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, de-identifiable data set,

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 signed ATHN Data Use Agreement will also be required.

Acknowledgment of Support

Articles, Abstracts, and Oral/Poster Presentations and Acknowledgements. Any articles (published and in progress), abstracts, or oral and poster presentations resulting from the awardee's CARE Award research must acknowledge the support of ATHN, the independent medical educational grant from CARE Award funders, the awardees' mentors, the ATHN-affiliated HTC, and appropriate attribution for the ATHN dataset as outlined in the applicant's award notification letter and/or the fully executed Grant Agreement contract. During and after the grant period, awardees are required to provide advance notification and copies to ATHN prior to submitting any articles for publication or abstracts for conferences, and prior to giving any oral or poster presentations resulting from the awardee's CARE Award research. During and after the grant period, awardees are also required to provide ATHN with a final published copy of any articles, abstracts, or oral and poster presentations resulting from their CARE Award research with the appropriate acknowledgements contained within the published copies.

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.

Required Presentation Awardees are required to present final results of their project at the ATHN Data Summit nearing or immediately following the grant period completion. The results may be presented as an abstract, poster or an oral presentation to be determined by ATHN.

4. ATHN Technical Assistance, Statistical Support for Pre-proposals and Full Proposals

A total of 10 hours for biostatistical services from ATHN are available at no cost to support the development of the pre- and full proposals. These support hours can be requested as needed in the period of time prior to submission of the full proposal. Requests for biostatistical support should be made with ample lead time.

Discussions with the ATHN biostatistician and preliminary data queries are encouraged for all applicants to help determine the feasibility of a study and refine potential research questions. Contact ATHN at support@athn.org to schedule your feasibility discussion.

Applicants who anticipate needing biostatistical consultation to develop their project's study design or statistical plan for the full proposal must request such consultation in their pre-proposal application. If the pre-proposal applicant is invited to submit a full proposal, the applicant will be able to contact an ATHN biostatistician to receive up to a total of 10 hours of consultation in the preparation of his/her full proposal application at no cost.

Services of an ATHN biostatistician may also be requested by CARE Award recipients during the duration of the funded project and there is a cost for such consultation. If this service is anticipated, the rationale for and percent effort allotted for the biostatistician must be sufficiently explained in the full proposal narrative and the expense must be reflected in the full proposal budget. Invited full proposal applicants must contact ATHN (support@athn.org) to request assistance in determining the number of hours of consultation needed and the associated cost.

5. 2020 CARE Award Program Timeline

Milestone	Date
Deadline for Pre-Proposals	March 3, 2020
Invitation for Full Proposals	April 2020
Full Proposals Due	June 10, 2020
Award Recipients Announced	August 2020
Final Reports Due	October 2021
Poster or Presentation at Data Summit 2021	Fall 2021

Questions

Send questions about the CARE Award to support@athn.org.

Submit a Pre-Proposal

Send a request for credentials for using the CARE Award online submission process to support@athn.org.

ATHNdataset Core Data Elements

DATA CATEGORY	CORE DATA ELEMENT
Record Status	Record Status - Active vs. Inactive
	Date Made Inactive
	Inactive Reason
Mortality Status	Mortality Status - Alive vs. Deceased
	Date of Death
	Primary Category of Death
	Primary Cause of Death
Demographics	Date of Birth
	Gender
	Race
	Ethnicity
	Education Level
	Employment Level
	Zip Code
Consents	ATHNdataset Patient Authorization
Insurance Information	Category
	Start Date
	Payer Name
	Type
Diagnoses	Primary Bleeding or Clotting Disorder Diagnosis Name
	Status
	Primary Diagnosis Indication
	Start Date
	Reason for Diagnostic Testing
Complications and Co-Morbidities	History of Other Diagnoses
	Inhibitor
	HIV
	Hepatitis A
	Hepatitis B
Surgeries/Procedures	Hepatitis C
	Date
	Surgery/Procedure Type

DATA CATEGORY	CORE DATA ELEMENT
Medications	Primary Bleeding or Clotting Disorder Medication Names
	Start Date
	Primary Regimen Indication
	Treatment Type
	Dose
	Frequency
	End Date
	Reason for Discontinuation
Immune Tolerance Regimen	Start Date
	End Date
	Response
Immunizations	Immunization Type
	Immunization Status
Bleed/Infusion Data	Product Usage
	Bleed Events
	First Product Exposure
	Historical Product Exposure
	First Bleed Information
	Infusion Administration History
Visit Information	Target Joint History
	Type of Visit
	Date of Visit
	Visit Disposition
Vital Signs	Report sent to PCP
	Weight
	Height (length for children)
Laboratory Tests	Baseline Diagnoses and Co-Morbidities
	Test Name
	Draw Date
	Lab Results

* ATHN Affiliates determine the data that is collected, managed and securely stored and transmitted using the Clinical Manager system. The ATHNdataset Core Data Elements that are listed above may change over time. ATHNdataset is a HIPAA-defined Limited Data Set stripped of all 16 categories of identifiers set forth in the HIPAA Privacy Rule. Data shared with ATHN as part of the ATHNdataset will be made available to ATHN and to approved researchers for research into the specific causes, prevention, treatment and social and economic impact of blood disorders, in compliance with all laws and regulations protecting the security of electronic health information and patient privacy.