

Request for Proposals (RFP)



2019 Dataset Research Engagement and ATHN Mentorship (“DREAM”) Award

- Applicants residing in the U.S. and working at U.S.-based, ATHN-affiliated HTC are eligible to apply for a 2019 DREAM Award. (If the applicant is not presently working at an ATHN-affiliated HTC, he/she is required to collaborate with a primary mentor who is working at an ATHN-affiliated HTC to be eligible.)
- Pre-proposals are due on or before **Friday, February 15, 2019 by 11:59 p.m. ET** as one pdf document emailed to HTRS at htrs@bcw.edu.
- Invited full proposals will be due on or before **Friday, May 31, 2019 by 11:59 p.m. ET** as one pdf document emailed to HTRS at htrs@bcw.edu.
- Awards will be announced in August, 2019 for 12-month projects running from October 1, 2019 through September 30, 2020, or 24-month projects running from October 1, 2019 through September 30, 2021.

HTRS and ATHN wish to thank Shire for making this award possible through an independent medical educational grant.

Program Summary

The Hemostasis and Thrombosis Research Society (“HTRS”) and the American Thrombosis and Hemostasis Network (“ATHN”) announce the availability of the **2019 Dataset Research Engagement and ATHN Mentorship (“DREAM”) Award**, supported by an independent medical educational grant from Shire.

The DREAM Award is offered through the collaboration of HTRS and ATHN. The award provides grants of \$50,000 USD over 12 months or \$100,000 USD over 24 months to enable young investigators residing in the U.S. to work with ATHN-affiliated, U.S.-based hemophilia and thrombosis treatment centers (“HTCs”) to conduct research using the national ATHNdataset under the guidance of experienced mentors.

The goals of the DREAM Award are to:

1. Advance the care of patients with bleeding and clotting disorders by funding research in the field of hemostasis and/or thrombosis, and
2. Combat the shortage of skilled academic physician researchers in non-malignant hematology in the U.S. by providing funding, mentorship, and career development support to early stage physician scientists pursuing academic research careers in non-malignant hematology.

The ATHNdataset is a HIPAA compliant, voluntary limited dataset, containing a subset of what is typically recorded in a patient's full medical record. As of March 2018, there are over 36,000 thousand patients who have opted in to allow their data to be included in the ATHNdataset. ATHN sponsors the ATHNdataset and supports HTC's in the routine collection of this demographic and clinical data. There are many data elements in the ATHNdataset; however there are a number of elements that comprise the ATHNdataset Core Data Elements. These core elements constitute the most complete data in the ATHNdataset. Non-core elements are also available for analysis, but in general are present in the ATHNdataset less frequently than the core elements. The terms "core" and "non-core" are used throughout this application to distinguish between the two categories of data elements.

Please also note the following:

- Multi-center collaboration is encouraged, if appropriate, to enhance the mentoring experience and/or to use or enhance the information in the ATHNdataset.
- Proposals may feature longitudinal, case/control, feasibility, quality improvement, comparative-effectiveness, cost-effectiveness initiatives, or other applicable initiatives of the applicant's choosing.
- A project timeline including measurable objectives to be reached by the end of the grant period must be included.
- A primary mentor, preferably working with the applicant at a U.S.-based, ATHN-affiliated HTC, must be secured prior to submitting a pre-proposal. If the applicant is not presently working at an ATHN-affiliated HTC, he/she must select a mentor who is working at an ATHN-affiliated HTC to be eligible. Ideally, a second mentor experienced in conducting dataset research/statistical analysis should also be secured. (If one mentor meets both requirements, then one mentor is sufficient for the purposes of the grant application.)
- The specific ATHNdataset core data elements that will be evaluated in the proposed study should be listed (a comprehensive list of core data elements appears on page 16 of this RFP and is also available at www.athn.org).
- Eligible proposals will utilize data contained in the ATHNdataset core data element, but applicants may also augment it with complementary non-core data to be collected in local or regional collaborations or analyses. While new data elements cannot be added solely for the purpose of a project, applicants may suggest additional outcomes that are not currently included as an ATHNdataset core data element that they plan to analyze or to collect from participating HTC's in a multi-center proposal. Applicants are allowed to include such an "exploratory" aim or objective in addition to a main goal, relating to non-core data elements but will not be penalized if they do not choose to include an "exploratory" aim. No more than one or two additional aims are recommended to assure the additional aims are feasible within the project timeline. A proposal that includes an exploratory aim must be 2-year proposal, as it is unlikely that a project of this nature could be accomplished in less than 2 years.

Funding Maximum and Grant Periods: The maximum grant for a 12-month award is \$50,000 USD; the maximum grant for a 24-month award is \$100,000 USD (or \$50,000 USD per year for two years). Twelve month awards will run from July 1, 2019 through June 30, 2020. Twenty-four month awards will run from July 1, 2019 through June 30, 2021.

Pre-proposal Application Deadline and Instructions: Submission of a pre-proposal is required as the first step in the DREAM Award application process on or before **Friday, February 15, 2019 at 11:59 p.m. ET. as one pdf document emailed to htrs@bcw.edu. You will receive a confirmation email for your submission. If you should not receive this confirmation within 72 hours, please contact us at 414-937-6569.**

Pre-proposals will be reviewed by members of the Joint Committee. Applicants will be asked to specify if they are seeking a one year or a two year award in their pre-proposal. HTRS and ATHN reserve the right to

determine the final number of DREAM Awards granted based on the quality of submitted proposals, the availability of grant funding, or other restrictions imposed by the educational grant supporter. Current funding will support one 12-month award and one 24-month award.

Before Submitting a Pre-proposal

1. Applicants are encouraged to visit the ATHN website (www.athn.org) to review the “ATHN Research Report Brief” 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 HTC to better understand the data collected by sites using the ATHN Clinical Manager.
3. Applicants are encouraged to view the recording of last year’s DREAM Award Submission Webinar, organized by ATHN, to review the program announcement, submission guidelines, and the ATHN Research Report Brief. The recording and the slide deck will be available at www.htrs.org and www.athn.org. You may also view the recording by going to the link below and entering your name and email. If you have any questions after viewing the recording, please contact ATHN at support@athn.org.

Watch 2018 Recording

<https://register.gotowebinar.com/recording/3477275177130899715>

4. Applicants are encouraged to email ATHN at support@athn.org if there are any questions or need for additional guidance related to the ATHNdataset. It is very important to determine if the data sought in your project is available in the dataset before moving ahead with an application.
5. Applicants should recognize that the ATHNdataset core data elements (see page 16 of this RFP) provide a powerful database that can be used as a starting point to answer a research question or address a quality initiative. The ATHNdataset can be amplified by innovative approaches (e.g. setting up a collaborative network of HTCs willing to collect and enter additional non-core data elements related to a specific topic or question). Examples of potential projects include:
 - **Von Willebrand Disease.** Consider treatment approaches in relation to baseline level in patients with VWD.
 - **Evaluating adherence to therapeutic recommendations.** Use Veritas Pro and compare interventions (motivational interviewing or others).
 - **Assessing the prevalence of overweight and obesity in participants affected by bleeding disorders.** Query weight-based dosing vs. ideal body weight and compare to annual bleed rate and cost.
 - **Testing improvements in transition of care.** Document time to first visit in adult HTC, adherence to prophylaxis and bleed rate before and after transition.
 - **Documenting ITI treatment outcomes.** Retrospectively document dosing, bleeding episodes, infection rate, success, and time to success.

Eligibility Requirements

Since ATHN is a U.S.-based network, applicants must either be working at U.S.-based, ATHN-affiliated HTC or be working with a mentor who is located at an ATHN-affiliated HTC to be eligible for a 2019 DREAM Award. The HTC must be an ATHN Affiliate in good standing, enrolling patients in the ATHNdataset at the time of application.

1. Applicants must hold an MD or DO and be either:

- Early-stage investigators (junior faculty/junior attending) who: 1) reside in the U.S. and work at U.S.-based, ATHN-affiliated HTCs, and 2) are within seven years of completing adult or pediatric hematology/oncology fellowships as of July 1, 2019. (If the applicant is pursuing a career in hemostasis/thrombosis but is not presently working at an ATHN-affiliated HTC, he/she is required to collaborate with a primary mentor who is working at an ATHN-affiliated HTC to be eligible.)
- Second- or third-year fellows as of July 1, 2019 who reside in the U.S. and are enrolled in accredited, U.S.-based adult or pediatric hematology or hematology/oncology fellowship programs. (If the fellow's institution is not a U.S.-based, ATHN-affiliated HTC, they are required to collaborate with a primary mentor who is working at an ATHN-affiliated HTC to be eligible.) Fellows invited to submit full proposals are required to include a letter of support from their fellowship program director as part of the full proposal application. The letter should state that the applicant is in good standing and has sufficient time to conduct the proposed research as part of his/her fellowship program.

In addition:

- Only fellows and/or early-stage investigators associated with non-commercial institutions are eligible to apply.
- U.S. citizenship is not required, but awardees must reside in the U.S. during the grant period and be working at or with a U.S.-based, ATHN-affiliated HTC.
- Applicants are encouraged to become members of HTRS at www.htrs.org, if not already. Fellows are eligible for free membership for the duration of their fellowship. Membership status will not affect selection.

Eligibility Regarding Applying for More than One HTRS Award

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

- Applicants considering applying in the same year for the HTRS/ATHN DREAM Award and additional HTRS awards with overlapping grant periods should contact HTRS at HTRS@bcw.edu to discuss before preparing the applications. (Applicants generally may not receive more than one HTRS award with overlapping grant periods in a given year.)
2. **Primary mentors** must be established clinicians, epidemiologists, or related researchers working in hemostasis/thrombosis at U.S.-based, ATHN-affiliated HTC who:
- Agree to mentor an applicant presently working at their ATHN-affiliated HTC
 - OR**
 - Agree to mentor an applicant who is not physically located at their ATHN-affiliated HTC, but who is pursuing a career in hemostasis/thrombosis
 - AND**
 - Are familiar with both the goals of the applicant’s proposed research and the mentoring requirements of the DREAM Award

One primary mentor, preferably working with the applicant at a U.S.-based, ATHN-affiliated HTC, must be secured prior to submitting a pre-proposal. If the applicant is not presently working at an ATHN-affiliated HTC, he/she must select a mentor who is working at an ATHN-affiliated HTC to be eligible.

3. Ideally, a **second mentor** experienced in conducting dataset research/statistical analysis should also be secured. (Second mentors are not required to be associated with an ATHN-affiliated HTC.) If the applicant’s primary mentor is experienced in conducting dataset research/statistical analysis, then one mentor is sufficient for the purposes of the grant application.

If the applicant is invited to submit a full proposal, a formal letter of support is required from each mentor.

Available Funding and Use of Funds

DREAM Award funds may be applied to the applicant’s salary (commensurate with academic rank at their appointing institution) and other direct project costs, as well as up to 8% of the total project budget in indirect costs, if requested by the institution. The maximum grant for a 12-month award is \$50,000 USD; the maximum grant for a 24-month award is \$100,000 USD (or \$50,000 USD per year for two years). Applicants must identify if they are seeking a 12-month or 24-month award in their pre-proposal.

Funding will be distributed in three payments, with the first payment paid within 30 days of the signing of the Grant Agreement contract. Funding for the second six months of a 12-month grant or the second year of a 24-month grant is contingent on the submission and successful review of a required six month or one year Progress Report by the Joint Committee. The final payment is contingent on the submission and successful review of a required Final Report by the Joint Committee.

If indirect costs (institutional overhead or hospital/research facility fees) are requested by the applicant’s HTC as part of the project budget, the amount requested for indirect costs may not exceed 8% of the total project budget, or cause the total project budget to exceed \$50,000 USD per year for both 12-month or 24-month grants.

Up to \$1,000 of the direct costs of the project budget may be earmarked to support travel expenses for the applicant to attend a well-recognized professional meeting (preferably the annual ATHN Data Summit, the HTRS Symposium, or the Thrombosis and Hemostasis Summit of North America, known as THSNA) to present an abstract or oral report on their funded research project. (Eligible travel expenses include meeting registration, air and ground travel, lodging, or per diem costs up to \$1,000 total.)

Statistical consultation services from ATHN for the proposed project may be supported by the successful grant if this is of benefit to the applicant and the project. (See section below)

The 2019 DREAM Award is funded by an independent medical educational grant to HTRS and ATHN from Shire. Successful applicants are required to acknowledge the support of HTRS, ATHN, Shire (or other grant supporters, if applicable), their mentors, their ATHN-affiliated HTC, other ATHN-affiliated HTCs involved in the project, and the appropriate attribution for the ATHN dataset in publications and presentations related to their award. Specific instructions for acknowledgment will be communicated to recipients in their award notification letters and/or Grant Agreement contracts.

Request for Statistical Support in Pre-proposals and Full Proposals

An ATHN biostatistician is available at no cost to applicants who request consultation. Discussions with the ATHN biostatistician and preliminary data queries are encouraged to help determine feasibility of a study and refine a potential research question.

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 consultation in the preparation of his/her full proposal application at no cost.

In addition, the services of an ATHN biostatistician may be requested to provide consultation to DREAM Award recipients during the duration of the funded project; however, 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 to request assistance in determining the number of hours of consultation needed and the cost.

Current and Pending Support Requirement

Applicants must report all current and pending funding sources for their proposed projects in the full proposal narrative and budget. In the event that additional funding becomes available to cover salary support or research costs for the project, applicants will be asked to provide documentation to HTRS/ATHN that requested budgetary items do not overlap. If the new funding covers all or substantially all of the costs of the project, any grant funds that remain unused must be returned to HTRS/ATHN. Specific details of this requirement are included in the Grant Agreement contract.

Other Conditions and Responsibilities

Submission of a DREAM Award full proposal implies acceptance of the following conditions by the applicant, the mentors, and the U.S.-based ATHN-affiliated HTC:

1. Required Grant Agreement. Upon notification of a DREAM award, awardees are responsible for providing HTRS/ATHN with the name and contact information of the appropriate financial or legal representative at the recipient HTC/institution who should receive the Grant Agreement contract. The awardee, his/her primary mentor and co-mentor, the recipient HTC/institution's representative, and representatives of HTRS and ATHN are required to sign a Grant Agreement contract prepared by HTRS/ATHN before award funds are dispersed.
2. ATHN Data Sharing and Use Agreement: Upon acceptance of the DREAM Award, the awardee will agree to and sign the ATHN Data Sharing and Use Agreement. Any questions regarding this agreement should be directed to support@athn.org.
3. Change in Status. The awardee is responsible for providing HTRS with written notice of any change in status related to their project or career path at any time during the course of the project period. Change in status notification letters are subject to review and approval by HTRS. While most change requests are negotiable, it should be noted that a change in career direction from an academic research institution to commercial industry, for example, is not permitted per eligibility requirements and will result in the awardee returning the balance of his/her funding. The exact conditions and instructions for submitting a change in status report are outlined in the Grant Agreement contract.
4. Award Administration. The day-to-day administration of DREAM Awards is the responsibility of the recipient HTC/institution. As such, the recipient HTC/institution issues award funds as outlined in the approved project budget according to its own procedures and payment schedules. Funds are not sent to awardees directly.
5. Rights and Welfare of Human Subjects. ATHNdataset research is not construed as human subject research because identifiers are stripped from the data, consistent with the definition of a HIPAA-compliant limited data set.
6. Animal Research: Animal research is not allowed under this grant.
7. 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 DREAM Award research must acknowledge the support of HTRS and ATHN, the independent medical educational grant from Shire (or other grant supporters, if applicable), the awardees' mentors, the ATHN-affiliated HTC, other ATHN-affiliated HTCs involved, and appropriate attribution for the ATHNdataset 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 HTRS/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 DREAM Award research. During and after the grant period, awardees are also required to provide HTRS/ATHN with a final published copy of any articles, abstracts, or oral and poster presentations resulting from their DREAM Award research with the appropriate acknowledgements contained within the published copies.
8. Required Reports. Per the fully executed Grant Agreement contract, awardees are required to submit two formal reports using templates provided by HTRS/ATHN: 1) a Progress Report after the first six months (for one-year projects) or after the first year of research (for two-year projects), and 2) a Final Report within three months of the completion of the grant period. HTRS/ATHN is required

to share these reports with Shire or other grant supporters, if applicable. As such, awardees should prepare their reports to include acknowledgment of Shire (or other grant supporters, if applicable) as outlined in their Grant Agreement contracts. Required reports must also include a list of any articles (published and in progress), abstracts, or oral and poster presentations resulting from the DREAM Award research, with copies appended. Awardees accept primary responsibility for understanding when reports are due and for following submission instructions provided by HTRS/ATHN.

Preparing a Pre-proposal

Pre-proposals are a required first step in the DREAM Award submission process. Applicants are required to follow all formatting instructions and submit their application as one pdf document to htrs@bcw.edu. Submissions should be received on or before **Friday, February 15, 2019 by 11:59 p.m. ET.**

You will receive a confirmation email for your submission. If you should not receive this confirmation within 72 hours, please contact us at 414-937-6569.

Components of a Complete Pre-proposal

1. Application Form

The DREAM Award Pre-proposal Application Form is a required part of the application process and should be included before the pre-proposal narrative as one pdf document. Please email htrs@bcw.edu if you would like an Application Form.

2. Pre-proposal Narrative (2 pages maximum, excluding references and list of collaborating HTC's, if applicable)

The pre-proposal narrative should be included after the Application Form as one pdf document.

The two-page narrative should address the following points. Reviewers will use these points as guidelines to assess the quality of the a) applicant; b) mentor(s) and environment; c) science; d) research plan and e) role/benefit of the ATHNdataset.

a. Quality of applicant should include:

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

b. Quality of mentor(s) and environment should include:

- i. Description of the primary mentor and co-mentor's qualifications

- ii. Quality and appropriateness of the research environment as it pertains to the applicant and project
 - iii. A clear explanation of the applicant’s role vs. the role of the primary mentor and co-mentor in the research concept, design, and implementation. If relevant, specify the specific parts of the project to be carried out by the applicant as opposed to the primary mentor and co-mentor
 - iv. If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance
- c. **Quality of the science** should include:
- i. Background, scientific merit, significance, and impact of the project
 - ii. Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects.
- d. **Quality of the research plan** should include at least brief reference to the following, with one or more aspects presented in greater detail. It is understood that where greater detail is provided may vary with the specific proposal:
- i. Hypotheses and aims/objectives of the proposed research. Applicants are encouraged to review the “ATHN Research Report Brief” available at www.athn.org to understand the number and types of data in the ATHNdataset. Applicants should work with the ATHN Administrator at their HTC to review core and non-core data elements as captured within the ATHN Clinical Manager. Applicants are allowed to include an “exploratory” aim (no more than one or two are recommended) relating to non-core data elements, but will not be penalized if they do not choose to include an “exploratory” aim. A proposal that includes an exploratory aim must be 2-year proposal, as it is unlikely that a project of this nature could be accomplished in less than 2 years.
 - ii. Study design and methodology
 - iii. Discussion of feasibility; realistic project timeline
 - iv. Potential limitations and how to address them
 - v. Statistical plan and/or considerations, if only preliminarily. If applicable, preliminary data should be included.
 - vi. Plan for obtaining statistical support. Applicants may request consultation from ATHN to develop their research study design and statistical plan at no cost, which is required for the full proposal, and/or to implement their funded project at a cost that must be built into their full proposal project budget. The rationale for this request must be included in the pre-proposal. Applicants who do not request consultation from ATHN in the pre-proposal must then identify in the pre-proposal what statistical resources are available within their own institutions/HTCs or locally. (See Statistical Support Requirements on page 6.)
- e. **Role and Benefit of the ATHNdataset** should include:
- i. Clear explanation of how the ATHNdataset will be used to address objectives
 - ii. Listing of specific core data elements used in the study (a comprehensive list of core data elements appears on page 16 of this RFP).
 - iii. Adequate plan for enriching the data to fulfill the project goals by validating and enhancing the collection of core and non-core data at applicant HTC and/or through participating HTCs. **Note that a plan asking HTCs to add data that is not commonly or**

easily added is not helpful; a better plan is to ask HTC's to complete and validate their data. Any questions related to this should be directed to support@athn.org.

- iv. If there is proposed collection of data elements that are outside of the scope of core or non-core that must be collected or validated through participating HTC's, justification & feasibility must be provided for each data element.
- v. The pre-proposal should include a list of collaborating HTC's, if any, and their respective roles. This may be listed on a separate additional page.

Pre-proposal Formatting Instructions for the Narrative

If the applicant has questions related to the formatting instructions below, please contact HTRS at htrs@bcw.edu no later than **Friday, February 8, 2019 by 11:59 p.m. ET**, one week in advance of the pre-proposal deadline. **Submitted pre-proposals will be deemed ineligible if instructions are not followed.**

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

Pre-proposal Review Process

Pre-proposals submitted by **Friday, February 15, 2019 by 11:59 p.m. ET** to htrs@bcw.edu will be reviewed by members of the Joint Committee, a peer review committee comprised of HTRS and ATHN members. Any reviewer with a direct conflict of interest (such as serving as a current mentor or co-mentor to one of the applicants) is recused from the entire review process. Any reviewer with an indirect conflict of interest (such as a close personal or professional relationship with any applicant, or previous involvement in any applicant's proposed project) is recused from reviewing the specific application in question.

The Joint Committee will perform a pre-proposal review of the data submitted by each applicant. The Committee's goal is to advance only the most competitive proposals to the full proposal round to be considered for the limited pool of grant funding available.

Pre-proposal Review Timeline

The Joint Committee completes a thorough review of all submitted pre-proposals. If the pre-proposal is favorably reviewed by the Committee, the applicant will be informed within approximately two months of the pre-proposal submission deadline that a full proposal is requested. HTRS/ATHN will make every effort to notify successful pre-proposal applicants as quickly as possible to allow applicants the maximum amount of time to prepare full proposals.

Full Proposal Application Guidelines

Applicants are invited to submit full proposals by the Joint Committee as a result of successful pre-proposal submission and review.

Note that the project outlined in the Full Proposal must be substantially the same as the project described in the Pre-proposal.

Invited applicants are required to follow all formatting instructions and submit their application as one pdf document to htrs@bcw.edu on or before **Friday, May 31, 2019 at 11:59 p.m. ET.**

You will receive a confirmation email for your submission. If you should not receive this confirmation within 72 hours, please contact us at 414-937-6569.

Components of Complete Full Proposal

1. Application Form

The DREAM Award Full Proposal Application Form is a required part of the application process and should be included with all the Full Proposal documents as one pdf document. Please update the form fields that were submitted in your pre-proposal application form, if necessary or you may request a new form from htrs@bcw.edu.

The following documents should be included after the Application Form as one pdf document in this order.

2. Background and Career Goals Statement (one page maximum)

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

The Background and Career Goals Statement should include:

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

3. **Project Narrative** (five pages maximum, excluding references)

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

- a. **Quality of mentor(s) and environment** should include:
 - i. Description of the primary mentor and co-mentor's qualifications
 - ii. Quality and appropriateness of the research environment as it pertains to the applicant and project
 - iii. A clear explanation of the applicant's role vs. the role of the primary mentor and co-mentor in the research concept, design, and implementation. If relevant, specify the specific parts of the project to be carried out by the applicant as opposed to the primary mentor and co-mentor
 - iv. If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance

- b. **Quality of the science** should include:
 - i. Background, scientific merit, significance and impact of the project
 - ii. Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects

- c. **Quality of the research plan** should include clear statements of:
 - i. Hypotheses and aims/objectives of the proposed research. Applicants are allowed to include an "exploratory" aim (no more than one or two are recommended) relating to non-core data elements but will not be penalized if they do not choose to include an "exploratory" aim. A proposal that includes an exploratory aim must be 2-year proposal, as it is unlikely that a project of this nature could be accomplished in less than 2 years.
 - ii. Study design and methodology; the project design should be appropriate to test proposed hypotheses. Project methods should support proposed aims.
 - iii. Feasibility analysis
 - iv. Potential limitations and how to address them
 - v. Future studies to be pursued if specific aims are accomplished
 - vi. Statistical plan and/or considerations. Patient or sample numbers and statistical methods should be identified. If applicable, preliminary data should be included.
 - vii. Plan for obtaining statistical support. Applicants may request consultation from ATHN to implement their project, but must reflect the rationale and percent effort for such support in their project budget since there is a cost for this support. Applicants must contact ATHN to request assistance in determining the number of hours of support needed and the cost. Applicants who do not indicate the need for consultation from ATHN must identify other statistical resources.
 - viii. Human subject protections should be appropriately described, if applicable
 - ix. A project timeline Please justify why you are requesting a one year award vs. a two year award, i.e. for one-year awards, justify why the project can be done in one year vs. two, and for two-year awards, justify why the project require two years to complete. Applicants

for two-year awards should specify what will be accomplished in Year One versus what will be accomplished in Year Two.

d. **Role and Benefit of the ATHNdataset** should include:

- i. Clear explanation of how the ATHNdataset will be used to address aims/objectives.
- ii. Listing of specific core data elements used in the study (a comprehensive list of core data elements appears on page 16 of this RFP).
- vi. Adequate plan for enriching the data to fulfill the project goals by validating and enhancing the collection of core and non-core data at applicant HTC and/or through participating HTCs. **Note that a plan asking HTCs to add data that is not commonly or easily added is not helpful; a better plan is to ask HTCs to complete and validate their data. Any questions related to this should be directed to support@athn.org.**
- iii. If there is proposed collection of data elements that are outside of the scope of core or non-core that must be collected or validated through participating HTCs, justification & feasibility must be provided for each data element
- iv. The pre-proposal should include a list of collaborating HTCs, if any, and their respective roles. This may be listed on a separate additional page.

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

5. A copy of the **current NIH Biosketch** for each mentor.

6. **Letters of Support from the mentors** outlining:

- a. The strengths of the applicant and any challenges that the applicant may face as a DREAM Award recipient.
- b. The research facilities and resources available to the applicant.
- c. A clear explanation of the applicant's role vs. the role of the mentors in the research concept, design, and implementation of the study. If relevant, identify the specific parts of the project to be carried out by the applicant, as opposed to the mentors.
- d. The nature of the week-to-week interactions between the applicant and the mentors. For those applicants not physically located at the mentor's HTC, the mentor should describe evidence of an appropriate communication and collaboration plan.
- e. In what ways you have mentored and plan to mentor the applicant to improve the scientific writing of the full proposal, and future scientific writing more generally.

7. **Letter of Support as follows:**

- a. For Fellows, the letter should be from the fellowship program director, stating that the candidate is in good standing and eligible for the award, agreeing to the percentage of time the candidate spends on research while enrolled in his/her fellowship program, and committing institutional support for the proposed project.
- b. For Junior Attending/Junior Faculty, the letter should be from the current department chairperson or division chief supporting the applicant's research and committing institutional support for the proposed project.

8. Project Budget and Addendum to Budget

The expenses below are permitted by HTRS/ATHN as part of the project budget, which may not exceed (and should preferably be equal to) a total of \$50,000 USD for a 12-month award and \$100,000 USD for a 24-month award. (Full Proposal applicants are required to use the budget template provided by HTRS/ATHN.)

- a. Direct Project Costs including:
 - Salary and fringe benefits for the applicant proportional to his/her percent effort on the project (commensurate with academic rank at their appointing institution).
 - Salary and fringe benefits for personnel required to implement the research project, if applicable
 - Equipment and supply expenses necessary to fulfill the project's specific aims
 - Registration, travel, and lodging fees (up to \$1,000) for the awardee to attend a well-recognized professional national or international meeting such as the ATHN Data Summit, HTRS Symposium, or THSNA Summit to present the results of their DREAM Award research in an abstract or oral session. (DREAM Award 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/ATHN in advance as essential to the Awardee's project outcome.)
 - Consultant costs for statistical or data management support
 - Collaborating HTC(s)' costs

- b. Indirect Costs/Facilities and Administrative Costs of up to 8% of the direct costs not to exceed \$3,704 USD for a 12-month award and \$7,408 for a 24-month award. If indirect costs are requested by the awardee's institution as part of the project budget, the line item for indirect costs may not exceed 8% of the total project direct costs, or cause the total project budget to exceed \$50,000 USD for a 12-month award or \$100,000 USD for a 24-month award.

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

- a. An explanation and justification of each line item requested in the budget template.
- b. List other current and pending funding sources for the proposed project, if any, as well as what expenses will be covered by the additional funding.
- c. A brief discussion of alternatives if this additional funding is not secured.

Full Proposal Formatting Instructions for the Background and Career Goals Statement and Project Narrative

If the applicant has questions related to the formatting instructions below, please contact HTRS at htrs@bcw.edu no later than **Friday May 24, 2019 by 11:59 p.m. ET**, one week in advance of the full proposal deadline. **Submitted full proposals will be deemed ineligible if instructions are not followed.**

1. Limit the background and careers goals statement to a maximum of one page.
2. Limit the project narrative to a maximum of five pages, excluding references.
3. Project narrative references:
 - a. May be listed separately from the narrative but should not exceed two additional pages
 - b. Must be relevant
 - c. Must be listed in the order in which they appear in the full proposal

- d. Must list more than just the first author
- e. Must have **applicant's name bolded** and mentors' names underscored
4. Use an NIH-approved font (Arial, Georgia, Helvetica, or Palatino Linotype), no less than 11 points in size, and 1-inch page margins for all documents.
5. Single or double spacing is acceptable.
6. Only generic names of products/services are allowed; names of brand names and specific companies should not be used.

Full Proposal Review Process

Full proposals submitted on or before **Friday, May 31, 2019 at 11:59 pm ET** to htrs@bcw.edu will be reviewed by members of the Joint Committee. Any reviewer with a direct conflict of interest (such as serving as a current mentor or co-mentor to one of the applicants) is recused from the entire review process. Any reviewer with an indirect conflict of interest (such as a close personal or professional relationship with any applicant, or previous involvement in any applicant's proposed project) is recused from reviewing the specific application in question.

The Joint Committee will perform the full proposal review based on data submitted by each applicant. The Committee's goal is to select the most competitive proposals for funding. HTRS/ATHN regrets that due to the limited funding available, we are unable to award grants to all applicants.

Notification of Grant Awards

Notification of final award decisions will be made by August 2019 for 12-month projects running from October 1, 2019 through September 30, 2020 or 24-month projects running from October 1, 2019 through September 30, 2021. Award funds will be disbursed within 30 days of the date of execution of the legal Grant Agreement contract between HTRS/ATHN and the recipient HTC/institution. The awardee will be required to sign the ATHN Data Sharing and Use Agreement upon acceptance of the DREAM Award and before access to the ATHNdataset is granted.

Questions?

Questions about the preparation and submission of 2019 DREAM Award pre-proposals and invited full proposals can be directed to Laura Mott at htrs@bcw.edu or (414) 937-6569.

Applicants are encouraged to contact the ATHN Administrator at their HTCs to better understand the data elements with the ATHN Clinical Manager and the ATHNdataset.

Applicants are also encouraged to email ATHN at support@athn.org if there are any questions or need for additional guidance related to the ATHNdataset.

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
Consents	ATHNdataset Patient Authorization
	Insurance Information
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
	Hepatitis C
Surgeries/Procedures	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
Immune Tolerance Regimen	End Date
	Reason for Discontinuation
	Start Date
Immune Tolerance Regimen	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
	Target Joint History
Visit Information	Type of Visit
	Date of Visit
	Visit Disposition
	Report sent to PCP
Vital Signs	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.

