

Request for Proposals (RFP)



2017 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 2017 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.)
- Applicants who have previously received HTRS Mentored Research or Clinical Fellowship Awards are eligible to submit for a 2017 DREAM Award as long as the grant periods do not overlap.
- Applicants interested in submitting a pre-proposal for a 2017 DREAM Award should email htrs@bcw.edu to request the pre-proposal application form.
- Pre-proposals are due on or before **Wednesday, June 1, 2016 by 6:00 p.m. ET**. Pre-proposals should be emailed as one PDF document to htrs@bcw.edu with the subject line “HTRS/ATHN DREAM Award Pre-proposal Submission.”
- Invited full proposals will be due on or before **Monday, August 29, 2016 by 6:00 p.m. ET**. They should be emailed as one PDF document to htrs@bcw.edu with the subject line “HTRS/ATHN DREAM Award Full Proposal Submission.”
- Awards will be announced in October for 12-month projects running from July 1, 2017 through June 30, 2018, or 24-month projects running from July 1, 2017 through June 30, 2019.

HTRS and ATHN wish to thank Baxalta US Inc. for making this award possible through a medical education grant.

Program Summary

The Hemostasis and Thrombosis Research Society (“HTRS”) and the American Thrombosis and Hemostasis Network (“ATHN”) announce the availability of the **2017 Dataset Research Engagement and ATHN Mentorship (“DREAM”) Award**, supported by a medical education grant from Baxalta US Inc.

The DREAM Award is offered through the collaboration of HTRS and ATHN. The award provides grants of \$50,000 over 12 months or \$100,000 over 24 months to enable young investigators residing in the U.S. to

work with ATHN-affiliated, U.S.-based hemophilia treatment centers (“HTCs”) to conduct research using the national ATHNdataset under the guidance of experienced mentors.

The goal of the DREAM Award is to advance the care of patients with bleeding and clotting disorders by funding research in the field of hemostasis. Multi-center collaboration is encouraged, if appropriate, to enhance the mentoring experience and/or to use or enhance the information in the ATHNdataset.

- Eligible proposals will utilize data from the existing ATHNdataset, but applicants may also augment it with complementary data to be collected in local or regional collaborations or analyses.*
- 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.) Applicants who need assistance from HTRS or ATHN to find a mentor experienced in database research and/or statistical analysis should state this request in their pre-proposal. If the pre-proposal is advanced by the HTRS/ATHN Joint Scientific Review Committee (“Joint Committee”) to a full proposal application, the applicant will be contacted so assistance can be provided to identify and secure a second mentor.
- The specific CORE data elements of the ATHNdataset that will be evaluated in the proposed study should be listed (a comprehensive list of CORE elements appears on page 15 of this RFP and is also available at www.athn.org).
- Award recipients will be given access to the ATHNdataset after signing the ATHN Data Sharing and Use Agreement. (Available for review at www.athn.org)

*While new data elements cannot be added solely for the purpose of a project, applicants may suggest additional outcomes or laboratory tests not currently in the CORE dataset that they plan to analyze or to collect from participating HTCs in a multi-center proposal. Applicants are encouraged to include such an “exploratory” aim or objective in addition to a main goal, relating to data not necessarily in the CORE; however, no more than one or two additional aims are recommended to assure the additional aims are feasible within the project timeline.

Funding Maximum and Grant Periods: The maximum grant for a 12-month award is \$50,000; the maximum grant for a 24-month award is \$100,000 (or \$50,000 per year for two years). Twelve month awards will run from July 1, 2017 through June 30, 2018. Twenty-four month awards will run from July 1, 2017 through June 30, 2019.

Pre-proposal Application Deadline and Instructions: Submission of a pre-proposal is required as the first step in the DREAM Award application process. Pre-proposals should be saved as one PDF document and emailed to htrs@bcw.edu with the subject line “HTRS/ATHN DREAM Award Pre-proposal Submission” on or before **Wednesday, June 1, 2016 at 6:00 p.m. ET.**

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 either two 12-month awards or 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 (Data Manager) at their Affiliate HTC to better understand the data collected by sites using the ATHN Clinical Manager.
3. Applicants are encouraged to attend the ATHN pre-conference entitled “Studies & Opportunities to Facilitate Research Through ATHN” held from 3:00 p.m. – 5:00 p.m. on April 13, 2016 prior to the THSNA meeting in Chicago if they are attending THSNA. (Register at www.thsna.org.) Additionally, applicants are encouraged to attend a 2017 DREAM Award Submission Webinar, organized by ATHN, to review the program announcement, submission guidelines, and the ATHN Research Report Brief, or to ask questions about the ATHNdataset. The webinars will be held on **Friday, April 22, 2016 at 3:00 p.m. ET** and on **Wednesday, April 27, 2016 at 11:00 a.m. ET**. Register at: <https://attendee.gotowebinar.com/rt/2659342968082866436>. (Note: if the date for the webinar has passed, interested applicants can still view the slides presented during the webinar at www.htrs.org and www.athn.org.)
4. Applicants should recognize that the ATHNdataset CORE data elements (see page 15 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 dataset can be amplified by innovative approaches (e.g. setting up a collaborative network of HTCs willing to collect additional data related to a specific topic or question). Examples of potential projects include:
 - **Prophylaxis Use at HTCs.** A landmark paper indicated the importance of prophylaxis in promoting joint health and better clinical outcomes in individuals with hemophilia. Guidelines have been issued by the Medical and Scientific Advisory Committee of the National Hemophilia Foundation to support the adoption of prophylaxis into comprehensive hemophilia care. Yet the extent to which prophylaxis has been incorporated into care at HTCs and predictors of prophylaxis at HTCs remain unknown. A potential project might examine prophylaxis use by state, payer, age, or race, or over time in order to determine barriers to and gaps in care, as well as potential approaches from a public health perspective. *Healthy People 2020* (www.healthypeople.gov) or other quality measures could be similarly explored.
 - **Predictors of Joint Replacement Surgery in Hemophilia.** Joint replacement surgery is a common outcome in patients with hemophilia and joint disease. While this surgery can improve function and quality of life for patients, a goal is to prevent the need for joint replacement by preventing progression of joint disease. A potential project could look at predictors of joint replacement surgery by treatment, type, disease severity, BMI, demographics, comorbidities, etc.

- **Von Willebrand Disease Diagnosis.** A 2009 publication from the National Heart, Lung and Blood Institute titled “The Diagnosis, Evaluation, and Management of von Willebrand Disease” set forth precise guidelines for the diagnosis of von Willebrand disease; however, the extent to which these guidelines are used in clinical practice is not well established. In addition, the cutoff proposed by these guidelines is not clinical or evidence based; it is also not the same cutoff used in other countries, which tends to be higher (~.40 U/mL). Since baseline levels are now being entered into the ATHNdataset, this provides the opportunity to explore baseline levels of patients entered with the diagnosis VWD (i.e., VWD range, “low VWF range” or normal range by the National Institute of Health guidelines) and to look for predictors of entering the diagnosis with levels above 30% (e.g., demographic predictors, especially age or site predictors, are likely). Alternatively, applicants might explore treatment approaches in relation to baseline levels (DDAVP, antifibrinolytic therapy and/or VWF concentrate) and treatment by other cofactors such as HTC region and patient demographics and comorbidities.

Eligibility Requirements

Since ATHN is a U.S.-based network, applicants must either be working at U.S.-based, ATHN-affiliated HTCs or be working with a mentor who is located at an ATHN-affiliated HTC to be eligible for a 2017 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, 2017. (If the applicant is pursuing a career in hemostasis 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, 2017 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 who have previously received HTRS Mentored Research or Clinical Fellowship Awards are eligible to submit for a 2017 DREAM Award as long as the grant periods do not overlap.
- 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.

2. **Primary mentors** must be established clinicians, epidemiologists, or related researchers working in hemostasis 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
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.

Applicants who need assistance from HTRS or ATHN to find a second mentor experienced in database research and/or statistical analysis should state this request in their pre-proposal. If the pre-proposal is advanced by the HTRS/ATHN Joint Scientific Review Committee ("Joint Committee") to a full proposal application, the applicant will be contacted so assistance can be provided to identify and secure this mentor.

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. The maximum grant for a 12-month award is \$50,000; the maximum grant for a 24-month award is \$100,000 (or \$50,000 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 Year One 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 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 in Chicago, IL, 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 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 2017 DREAM Award is funded by a medical education grant to HTRS and ATHN from **Baxalta US Inc.** Successful applicants are required to acknowledge the support of HTRS, ATHN, Baxalta US Inc., their mentors, their ATHN-affiliated HTC, other ATHN-affiliated HTCs involved in the project, and the appropriate attribution for the 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 PhD biostatistician is available to applicants who request assistance. 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 services to develop their project's study design or statistical plan for the full proposal must request such assistance in their pre-proposal application.

If the pre-proposal is favorably reviewed by the Joint Committee, the applicant will be able to contact an ATHN-affiliated database expert/statistical consultant to receive assistance in the preparation of his/her full proposal application.

In addition, the services of the ATHN PhD biostatistician may be requested to assist DREAM Award recipients during the duration of the funded project. 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 be reflected in the full proposal budget.

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. (Available for review at www.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. ATHN dataset 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. Acknowledgment: Any publications, abstracts/posters, or presentations resulting from the awardee's DREAM Award research must acknowledge the support of HTRS and ATHN, the medical education grant from Baxalta US Inc., the awardees' mentors, the ATHN-affiliated HTC, other ATHN-affiliated HTCs involved, and appropriate attribution for the dataset as outlined in the applicant's award notification letter and/or the fully executed Grant Agreement contract. Awardees are required to provide HTRS with a copy of any publications, abstracts, or presentations resulting from their DREAM Award research during and after the grant period with the appropriate acknowledgments listed.
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 Baxalta US Inc. As such, awardees should prepare their reports to include acknowledgment of Baxalta US Inc. as outlined in their Grant Agreement contracts. Required reports must also include a list of any publications, abstracts/posters or presentations resulting from the DREAM Award research, with copies of publications, abstracts or presentations 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 incorporate both the application form and the pre-proposal narrative (described below) into one PDF document and submit it to htrs@bcw.edu on or before **Wednesday, June 1, 2016 by 6:00 p.m. ET.**

Applicants interested in submitting a pre-proposal for a 2017 DREAM Award should email htrs@bcw.edu to express their interest in applying and to request the Pre-proposal Application Form.

Components of a Complete Pre-proposal

1. Application Form

The DREAM Award Pre-proposal Application Form will be sent to interested applicants who email htrs@bcw.edu to request the form. Applications that do not include this required form will not be reviewed.

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

The two-page narrative should address the following points. Reviewers will use these points as guidelines to assess: 1) the overall quality of the proposed project, and 2) the potential of the project to further the applicant's career in hemostasis and/or thrombosis.

- a. Statement of a sincere commitment to an academic career in benign hematology and the relevance of the proposed research to the applicant's stated career goals.
- b. Brief listing of the qualifications of the mentors as well as 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 the implementation of the study. If relevant, applicants should identify the specific parts of the project to be carried out by the applicant, as opposed to the mentors. Those applicants not physically located at the mentor's HTC, must describe evidence of an appropriate communication and collaboration plan. Applicants who need assistance from HTRS /ATHN to find a mentor experienced in database research or statistical analysis must state this request in their pre-proposal. If the pre-proposal is advanced by the Joint Committee to a full proposal application, the applicant will be contacted to identify and secure this mentor.

- d. Background, justification and significance of the proposed research, including potential to contribute new knowledge to the field of hemostasis.
- e. Rationale and aims/measurable objectives of the proposed research. Applicants must clearly describe how they will use the ATHNdataset to address their proposed aims/measurable objectives. Applicants are encouraged to include an “exploratory” aim (no more than one or two are recommended) relating to data not necessarily in the CORE. Applicants are also encouraged to review the “ATHN Research Report Brief” available at www.athn.org to understand the number and types of records in the ATHNdataset. Applicants should work with the ATHN Administrator at their HTC to review CORE and non-CORE data elements as captured within Clinical Manager.
- f. The specific CORE data elements of the ATHNdataset that will be evaluated in the proposed study should be listed (a comprehensive list of CORE elements appears on page 15 of this RFP).
- g. A project timeline including aims/measurable objectives to be reached by the end of the grant period must be included.
- h. The research plan should include sufficient detail to allow reviewers to judge the potential for new knowledge to the field of hemostasis.
- i. Statistical considerations must be addressed in the pre-proposal narrative, if only preliminarily. Applicants may request statistical support from ATHN to develop their research study design and statistical plan, which is required for the full proposal, and/or to implement their project. The rationale for this request must be included in the pre-proposal. Applicants who do not request statistical support from ATHN in the pre-proposal must identify statistical resources available within their own institutions or locally in the pre-proposal.
- j. The pre-proposal should include a list of collaborating HTCs, if any, and their respective roles. This may be listed on a separate 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 Wednesday, **May 25, 2016 by 6:00 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 HTCs, 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 a basic font such as Times New Roman (no less than 11 points) 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 **Wednesday, June 1, 2016 by 6:00 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 the best possible pre-proposal review based on 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.

2017 DREAM Award pre-proposals will be judged according to the following criteria:

- Is the proposed research in keeping with the applicant's stated career goals? Will it help to advance the applicant's career?
- Are the mentors qualified to support the applicant in the proposed research? Is the primary mentor located at a U.S.-based, ATHN-affiliated HTC? For applicants not physically located at the mentor's HTC, is there an appropriate communication and collaboration plan? Does at least one of the mentors have expertise in database research or statistical analysis? If not, has the applicant requested assistance in finding such a mentor?
- Is the research environment appropriate?
- Does the pre-proposal clearly explain the roles of both the applicant and the mentors in the proposed research?
- Is the proposed research topic timely and relevant, i.e. in line with current priorities in the field of hemostasis? Does the project have the potential to generate new knowledge?
- Are the rationale and aims/measurable objectives of the proposed research clearly stated? Is an "exploratory" aim included?
- Does the applicant clearly describe how the proposed research will utilize the ATHNdataset?
- Are the specific CORE data elements of the ATHNdataset to be evaluated in the proposed study listed? (A comprehensive list of CORE elements appears on page 15 of this RFP.)
- Is a realistic project timeline developed, and is the project feasible within the proposed award period?
- Are statistical considerations appropriately identified? Is statistical support requested for the development of the full proposal and/or for project implementation? If so, is the rationale identified? If not, is a plan outlined for obtaining statistical support from other sources?

Pre-proposal Review Timeline

The Joint Committee completes a thorough review of all submitted pre-proposals, which can take some time. If the pre-proposal is favorably reviewed by the Committee, the applicant will be informed within 5-8 weeks 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. Invited applicants are required to follow all formatting instructions and incorporate all components of the full proposal (described below) into one PDF document with the subject line “HTRS-ATHN DREAM Award Full Proposal Submission” and submit it to htrs@bcw.edu on or before **Monday, August 29, 2016 at 6:00 p.m. ET.**

Components of Complete Full Proposal

1. Application Form

Invited full proposal applicants are required to update and re-submit their pre-proposal **Application Form** as part of their full proposal. Applicants should be sure to update the application date on the bottom of the form before re-submitting. (If you no longer have access to your previously submitted Application Form, please request a blank form from htrs@bcw.edu.) Applications that do not include this required form will not be reviewed.

2. Career Goals Statement (one page maximum)

The career goals statement should address the following points. Reviewers will use these points as guidelines to assess: 1) the ability of the applicant to conduct the proposed research, and 2) the potential of the applicant to build a successful career in hemostasis.

- a. Statement of a sincere commitment to an academic career in hemostasis
- b. Description of the applicant’s background and preparation for the proposed research
- c. Future career plans and the relevance of the proposed research to stated career goals.

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

The Project Narrative should address the following points. Reviewers will use these points as guidelines to review the full proposal narrative.

- a. Brief description of mentor qualifications, as well as research facilities and resources available to the applicant.
- b. The narrative should contain a clear explanation of the applicant’s role vs. the role of the mentors in the research concept and design, as well as the 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. Those applicants not physically located at the mentor’s HTC, must describe evidence of an appropriate communication and collaboration plan.
- c. Background, justification and significance of the proposed research, including potential to contribute new knowledge to the field of hemostasis.
- d. A statement of the project’s hypothesis and specific aims/measurable objectives, including how the ATHNdataset will be used to address these aims/objectives. Applicants are encouraged to include an “exploratory” aim (no more than one or two are recommended) relating to data not necessarily in the CORE. The specific CORE data elements of the ATHNdataset that will be evaluated in the proposed study should be listed (a comprehensive list of CORE elements appears on page 15 of this RFP).

- e. A project timeline including specific aims/measurable objectives to be reached by the end of the grant period must be included. 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 requires 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.
 - f. Feasibility analysis, with patient or sample numbers and statistical methods identified. Applicants may request statistical support from HTRS/ATHN to implement their project, but must reflect the rationale and percent effort for such support in their project budget. Applicants who do not indicate the need for statistical support from ATHN must identify other statistical resources.
 - g. Experimental design and methodology, potential limitations, and future studies envisioned if specific aims are accomplished.
 - h. If the research proposal requires additional funds, the narrative should describe the source of this funding (obtained or applied for) and should include a brief discussion of alternatives if additional funding requests are not successful.
 - i. If additional data must be collected in ATHN Clinical Manager or validated through participating HTC's, the narrative should specify these additional data elements and additional HTC's and provide justification and feasibility for each.
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.
 7. For applicants who are fellows, a **Letter of Support** from the fellowship program director stating the applicant is in good standing and eligible for the award, and agreeing to the percentage of time the applicant proposes to spend on research while enrolled in his/her fellowship program.
 8. **Budget:** The expenses below are permitted by HTRS/ATHN related to the research project. For two year awards, please break expenses down into a Year One budget and Year Two budget.
 - a. Salary and fringe benefits for the awardee proportional to percent effort on the project (commensurate with academic rank at their appointing institution). Salary and fringe benefits for personnel needed to carry out the proposed research, if applicable. Please do not list fringe benefits as a separate line item. If you would like the grant to cover a portion of the fringe benefits for key personnel, please include that amount with the salary cost as part of the same line item.
 - b. Equipment and supply expenses necessary to fulfill the project's specific aims.

- c. 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 budget, or cause the total project budget to exceed \$50,000 for a 12-month award or \$100,000 for a 24-month award.
- d. Registration, travel, and lodging fees for the awardee to attend a professional meeting such as the annual ATHN Data Summit, HTRS Symposium, or THSNA Summit to present the results of their DREAM Award research in an abstract or oral session.
- e. Consultant costs for statistical or data management support.
- f. Collaborating HTC(s)' costs.

Full Proposal Formatting Instructions for the 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 **Tuesday, August 23, 2016** by 6:00 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 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 a basic font such as Times New Roman (no less than 11 points) and 1-inch page margins for the career goals statement, narrative and references.
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 **Monday, August 29, 2016 at 6:00 p.m.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.

Applicants will be judged according to the following criteria:

- a. The quality and potential of the applicant, including the demonstration of a sincere commitment to a career as a physician researcher in hemostasis.
- b. The relevance of the research to the applicant's stated career goals.
- c. The quality and appropriateness of the mentors and research environment.
- d. The presence of a clear explanation of the applicant's role vs. the role of the mentors in the research concept, design, and implementation of the study. Those applicants not physically located at the mentor's HTC, must describe evidence of an appropriate communication and collaboration plan.

- e. The scientific merit of the research proposal and its potential to contribute new knowledge to the field of hemostasis.
- f. The role and benefit of the ATHNdataset in the proposed research.
- g. A statement of the project's hypothesis and specific aims/measurable objectives, including the role and benefit of the ATHNdataset in addressing these aims/objectives. Applicants are encouraged to include an "exploratory" aim (no more than one or two are recommended) relating to data not necessarily in the CORE.
- h. A description of the specific CORE data elements of the ATHNdataset to be evaluated in the proposed study are listed (a comprehensive list of CORE elements appears on page 15 of this RFP).
- i. Experimental design and methodology, potential limitations, and future studies envisioned if specific aims are accomplished.
- j. The adequacy and appropriateness of the statistical analysis plan, including whether statistical support from ATHN was requested to implement the project, and the rationale for such support. Applicants who do not indicate the need for statistical support from ATHN must identify other statistical resources.
- k. The accuracy and feasibility of the project budget.
- l. Project feasibility within timeframe and budget.

The Joint Committee performs the best possible 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, it is not possible to award grants to all applicants.

Notification of Grant Awards

Notification of final award decisions will be made by October 2016 for 12-month projects running from July 1, 2017 through June 30, 2018 or 24-month projects running from July 1, 2017 through June 30, 2019. 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 (or awardees) 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. (Available for review at www.athn.org)

Questions?

Questions about the preparation and submission of 2017 DREAM Award pre-proposals and invited full proposals can be directed to Lorilyn Jacobsen-Tews or Laura Mott at htrs@bcw.edu or (414) 937-6569. Applicants are also encouraged to contact the ATHN Administrator at their HTCs to better understand the data fields and the functionality of the ATHN Clinical Manager software.

Applicants interested in submitting a pre-proposal for a 2017 DREAM Award should email htrs@bcw.edu to request the pre-proposal application form.

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
Demographics	Primary Cause of Death
	Date of Birth
	Gender
Consents	Race
	Ethnicity
	Education Level
Insurance Information	Employment Level
	Zip Code
	ATHNdataset Patient Authorization
Diagnoses	Category
	Start Date
	Payer Name
Complications and Co-Morbidities	Type
	Primary Bleeding or Clotting Disorder Diagnosis Name
	Status
Surgeries/Procedures	Primary Diagnosis Indication
	Start Date
	Reason for Diagnostic Testing
Medications	History of Other Diagnoses
	Inhibitor
	HIV
Immunizations	Hepatitis A
	Hepatitis B
	Hepatitis C
Visit Information	Date
	Surgery/Procedure Type

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

