#### **REQUEST FOR PROPOSALS (RFP)**



# 2024 Dataset Research Engagement and ATHN Mentorship ("DREAM") Award

Applicants must work at participating ATHN Affiliate institutions to be eligible to apply for a DREAM Award.

- Pre-proposals are due on or before
- Invited proposals are due on or before
- 2024 award will be announced for 24-month project running from September 15, 2024 through September 14, 2026

## **Program Summary**

The Hemostasis and Thrombosis Society ("HTRS") and the American Thrombosis and Hemostasis Network ("ATHN") announce the availability of the 2024 Dataset Research Engagement and ATHN Mentorship ("DREAM") Award, supported by an independent medical education grant from Takeda.

The DREAM Award is offered through the collaboration of HTRS and ATHN. The award provides a grant of \$100,000 USD over 24 months to enable a young investigator working at a participating ATHN-affiliated hemophilia and thrombosis treatment center ("site") to conduct research using the national ATHNdataset under the guidance of an experienced mentor.

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
- 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, de-identified dataset, containing a subset of what is typically recorded in a patient's full medical record. As of December 2023, there are over 64,000 patients who have opted in to allow their data to be included in the ATHNdataset. ATHN sponsors the ATHNdataset and supports sites 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 data elements are also available for analysis but are present in the ATHNdataset less frequently. 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:

- 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 must be secured prior to submitting a pre-proposal. The primary mentor must work at an ATHN-affiliated site to be eligible but may work at a different institution than the applicant.
- 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 the last page of this RFP and is also available at <a href="https://athn.org/what-we-do/for-researchers/athndataset-core-data-elements.html">https://athn.org/what-we-do/for-researchers/athndataset-core-data-elements.html</a>. Eligible proposals must utilize data contained in the ATHNdataset core data elements. Applicants may augment core elements with complementary non-core data elements if these elements exist in the ATHNdataset in sufficient quantity and quality to meaningfully contribute to the aims of the proposal.

#### **Funding Maximum and Award Period**

The maximum amount for a 24-month award is \$100,000 USD. The award period is from September 15, 2024, through September 14, 2026.

#### **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. Proposals must be submitted through

ATHN's online application platform. Contact <a href="mailto:support@athn.org">support@athn.org</a> to request a link to the platform to begin your application.

Pre-proposals will be reviewed by members of the DREAM Review Panel. HTRS and ATHN reserve the right to determine the final number of DREAM Awards granted based on the quality of submitted proposals and availability of funding.

#### **Before Submitting a Pre-proposal**

It is very important to determine if the data required for your proposed project is available in the ATHNdataset before moving ahead with an application.

Below are the steps to take prior to submitting a DREAM pre-proposal:

**Step 1: Review the ATHNdataset Core Data Elements** on the last page of this RFP to become familiar with the type of data available (and therefore the types of projects that could be supported by the ATHN dataset).

#### Step 2: Meet with your ATHN Administrator

Applicants are strongly encouraged to meet with their on-site ATHN Administrator to better understand the data collected using the ATHN Systems. Applicants must review the ATHN dataset Report Brief available in Clinical Manager to become more familiar with the data elements available in the ATHN dataset.

Step 3: Email ATHN at <a href="mailto:support@athn.org">support@athn.org</a> to request access to begin an application.

Proposals are required to be submitted through ATHN's online application platform.

Applications are encouraged to email ATHN at <a href="mailto:support@athn.org">support@athn.org</a> if there are any questions or need for additional guidance related to the ATHNdataset.

# **Eligibility Requirements**

#### Site and Mentor Requirements

Applicants must work at a participating ATHN Affiliate site and secure a mentor who is located at an ATHN Affiliate site to be eligible for a 2024 DREAM Award. The site must be an ATHN Affiliate in good standing, enrolling patients in the ATHNdataset at the time of application.

#### **Applicant Requirements**

Applicants must hold an MD or DO and be either:

 Early-stage investigators (junior faculty/junior attending) who: 1) work at an ATHNaffiliated site, and 2) are within seven years of completing adult or pediatric hematology/oncology fellowships as of October 15, 2023. Second- or third-year fellows as of October 15, 2023, who reside in the U.S. and are
enrolled in accredited, U.S.-based adult or pediatric hematology or
hematology/oncology fellowship programs. 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.

#### Additional Requirements

- Only fellows and/or early-stage investigators associated with non-commercial institutions are eligible to apply.
- Awardees must be working at an ATHN-affiliated site.
- Applicants are encouraged to become members of HTRS at <a href="www.htrs.org">www.htrs.org</a>, if not already a member. 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 Award**

- Previous HTRS/ATHN DREAM Award recipients are **not** eligible to apply.
- Previous DREAM Award applicants who were not been selected to receive a DREAM
  Award and who continue to meet the DREAM Award eligibility requirements may submit
  a pre-proposal for the 2024 DREAM Award with the same project or a new project. If the
  application is 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 Scholar Award applicants or recipients who meet the DREAM Award eligibility requirements may apply for the DREAM Award if the award periods do not overlap. If the award periods overlap, the DREAM Award applicant should contact <a href="mailto:support@athn.org">support@athn.org</a> to confirm eligibility before preparing a DREAM Award application. (Applicants may not receive more than one HTRS-supported award with overlapping grant periods in a given year.)

#### Mentors

A primary mentor must be secured prior to submitting a pre-proposal. The primary mentor must work at an ATHN-affiliated site to be eligible but may work at a different institution than the applicant.

Primary mentors must be established clinicians, epidemiologists, or related researchers working in hemostasis/thrombosis. Persons who agree to mentor an applicant must be familiar with both the goals of the applicant's proposed research and the mentoring requirements of the DREAM Award. Additional co-mentors may participate, but one primary mentor is sufficient for the grant application.

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

# **Available Funding and Use of Funds**

Applicants are required to submit a project budget with their full proposal.

DREAM Award funds may be applied to direct project costs, including the applicant's salary (commensurate with their institutional academic rank). Up to 8% of the total project budget may be included as indirect costs, if requested by the applicant's institution. The total project budget may not exceed \$100,000 USD.

Award funding will be distributed in two payments, with the first payment paid within 30 days of the execution of the Grant Agreement contract. Funding for the second year of a 24-month grant is contingent on the submission and successful review of a one-year progress report by the DREAM Review Panel. The final payment is contingent on the submission and acceptance of a required final report by the DREAM Review Panel.

If indirect costs (institutional overhead or hospital/research facility fees) are requested by the applicant's institution 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 \$100,000 USD.

Up to \$1,000 of the direct costs of the project budget may be earmarked to support travel expenses for the applicant to attend the annual ATHN Data Summit and/or the HTRS biennial Scientific Symposium 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.)

The 2024 DREAM Award is funded by an independent medical education grant to ATHN from Takeda. Successful applicants are required to acknowledge the support received from the DREAM Award as well as their mentors, their ATHN-affiliated site, and other ATHN-affiliated sites involved in the project. Successful applicants are also required to include appropriate attribution for the ATHNdataset in publications and presentations related to their award. Specific instructions for acknowledgment will be communicated to recipients in their award notification letters and Grant Agreement contracts.

# **Biostatistical Support in Pre-proposals and Full Proposals**

A total of five (5) hours for biostatistical services from ATHN are available at no cost to applicants to support the development of pre- and full proposals; specifically, to help determine the feasibility of the study and refine potential research questions. These support hours must be requested prior to submission of a pre- or full proposal by contacting ATHN at <a href="mailto:support@athn.org">support@athn.org</a> and must be made by June 1, 2024.

Services of an ATHN biostatistician during the funded award period may also be requested by DREAM Award recipients. If the need for biostatistical support is anticipated during a funded project, the rationale for and percent effort allotted for the ATHN biostatistician must be sufficiently explained in the full proposal narrative and the expense must be reflected in the full proposal budget. Invited full proposal applicants must contact ATHN (support@athn.org) to request assistance in determining the number of hours of consultation needed and the associated cost before submitting the budgets required in their full proposal application.

#### **Current and Pending Support Requirement**

Full proposal applicants must report all current and pending funding sources for their proposed projects in their full proposal budgets.

Should funding from other sources become available to an applicant prior to the announcement of final DREAM Award recipients in this funding cycle, the applicant is required to provide written documentation to <a href="mailto:support@athn.org">support@athn.org</a> explaining how the new funding affects the budget submitted with the original full proposal application.

# Other Conditions and Responsibilities

Submission of a DREAM Award full proposal implies acceptance of the following conditions by the applicant, the mentors, and the ATHN-affiliated site:

- 1. Required Grant Agreement. In the application for a DREAM Award, applicants are required to provide ATHN with the name and contact information of the appropriate legal representative at their institution who would receive the Grant Agreement. ATHN will issue the Grant Agreement contract to the Recipient Institution for review within four (4) weeks of award notification. The awardee, his/her primary mentor and any comentors, the recipient site/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. <u>Required Kick-Off Call/Logistics Consultation</u>. Directly following award notification and in parallel with grant contracting, the awardee is required to meet virtually with HTRS and

ATHN award leadership to confirm key details of the project and the forthcoming data request to set realistic expectations and a timeline for data delivery.

- 3. <u>ATHN Data Sharing and Use Agreement</u>. 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 <a href="mailto:support@athn.org">support@athn.org</a>.
- 4. Change in Status. The awardee is responsible for providing ATHN with written notice of any change in status related to their project or career path at any time during the project period. Change in status notification letters are subject to review and approval by ATHN. 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.
- 5. <u>Award Administration</u>. The daily administration of DREAM Awards is the recipient site/institution's responsibility. As such, the recipient site/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.
- 6. <u>Rights and Welfare of Human Subjects.</u> The ATHNdataset is a de-identified dataset as defined by HIPAA.
- 7. Animal Research: Animal research is not allowed under this grant.
- 8. 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 and other grant supporters, the awardees' mentors, the ATHN-affiliated site, other ATHN-affiliated sites 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 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 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.

9. <u>Required Reports.</u> Per the fully executed Grant Agreement contract, awardees are required to submit **two formal reports using templates** provided by ATHN: 1) a Progress

Report after the first year of research and 2) a Final Report within three months of the completion of the grant period. 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 ATHN.

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

# **Post-Award Report Requirements**

The following table reflects a general timeline for post-award milestones. The timeline for the final awardee's specific project may vary slightly based on decisions made during the awardee's required Kick-off Call/Logistics Consultation.

MILESTONE	RESPONSIBLE PARTY	TIMEFRAME FOR COMPLETION
Grant Agreement Contract	ATHN and Recipient	Contract execution anticipated
	Site/Institution	in Quarter 4 of 2024
Initial Biostatistical Data	ATHN	Within 6 months of the date of
Delivered to Awardee		contract execution
Progress Report	Awardee and Recipient	October 15, 2025
	Site/Institution	
Final Report	Awardee and Recipient	January 15, 2026
	Site/Institution	

<u>Disclosure of HTRS/ATHN Compliance</u> with State or Federal Requirements per Open Payments: The Physician Payments Sunshine Act

The HTRS/ATHN DREAM Awards may be reportable by law to state or federal agencies under Open Payments: The Physician Payments Sunshine Act ("Sunshine Act"). HTRS/ATHN may be required to share information about recipient institutions, principal investigators, or other particulars of funded grants with the pharmaceutical companies that support our award programs. Such companies may deem grant information reportable per their policies related to the Sunshine Act.

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

#### PRE-PROPOSAL

# **Preparing a Pre-proposal**

Pre-proposals are a required first step in the DREAM Award submission process. Proposals will be submitted through ATHN's online application process. Contact <a href="mailto:support@athn.org">support@athn.org</a> to request a link to the application. Submissions should be received on or before

# **Components of a Complete Pre-proposal**

- Lay abstract/project Narrative (100 words)
- The completed online application
- A research concept that includes scientific background and rationale, main hypothesis and proposed research aims, characteristics of the study population, ATHNdataset core data elements of interest, methodology including statistical approach (not to exceed 2 pages)
- Name of mentor and their ATHN-affiliated site
- Brief description of mentor qualifications and role in the project

#### **Pre-proposal Narrative**

Reviewers will use the narrative 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.

# **Quality of Applicant should include:**

Background of the applicant

- 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.
- Relevance of the proposed research to the applicant's stated career goals.
- 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.

#### Quality of mentor(s) and environment should include:

- Description of the primary mentor and co-mentor's qualifications. A primary mentor, working at an ATHN affiliated site must be included. If a second mentor is added to assist with statistical analysis, that is acceptable but not required.
- Quality and appropriateness of the research environment as it pertains to the applicant and project.
- A clear explanation of the applicant's role vs. the role of the primary mentor and comentor 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.
- If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished at a distance.

# Quality of the science should include:

- Background, scientific merit, significance, and impact of the project
- Potential of the project to generate new knowledge and lead to further funding opportunities and additional research projects.

**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:

• Hypotheses and aims/objectives of the proposed research. Applicants should work with the ATHN Administrator at their site to review the "ATHN Research Report Brief" which contains the number and type of core and non-core data elements in the ATHNdataset as captured within the ATHN Systems. Applicants should clearly explain how their

project will use the ATHNdataset and what data elements will be analyzed. Please note that the use of other databases is not allowed. Any application proposing to use data collection system other than ATHN Systems will be deemed ineligible.

- Study design and methodology
- Discussion of feasibility; realistic project timeline and budget
- Potential limitations and how to address them
- Statistical plan and/or considerations, if only preliminarily. If applicable, preliminary data should be included.

Plan for obtaining statistical support. Applicants may request consultation for up to 5
hours from ATHN for their pre- and full proposal to develop their research study design
and statistical plan at no cost. To implement the statistical plan of their funded project
biostatistical support is supplied at a cost that must be built into the 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/
sites or locally.

Role and Benefit of the ATHNdataset should include a clear explanation of how the ATHNdataset will be used to address objectives and a listing of specific core data elements used in the study (a comprehensive list of core data elements appears on the last page of this RFP).

#### **Pre-proposal Review Process**

Pre-proposals submitted by will be reviewed by members of the DREAM review panel, a peer review committee comprised of HTRS and ATHN members. The panel'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**

If the pre-proposal is favorably reviewed by the panel, the applicant will be informed within approximately six 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. Invited applicants will be required to submit their Full Proposal application on or before

#### **FULL PROPOSAL**

#### **Components of Complete Full Proposal**

## **Online Application**

The DREAM Award Application is a required part of the application process and can be an update of the form fields that were submitted in your pre-proposal application.

The following will also be required in the online application:

# 1. Background and Career Goals Statement

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:

- Background of the applicant and preparation for the proposed research
- Demonstrated 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

# 2. Career development plan

- Future career goals/plans
- Relevance of the proposed research to the applicant's stated career goals
- 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** (5 pages maximum, excluding references)

The 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 Preproposal, 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 almentor(s) and environment; b) science; c) research plan; and d) role/benefit of the ATHNdataset.

#### Quality of mentor(s) and environment should include:

- Description of the primary mentor and co-mentor's qualifications
- Quality and appropriateness of the research environment as it pertains to the applicant and project
- 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
- If the mentor/co-mentor are at a different institution, a communication plan must indicate how the mentoring will be accomplished remotely

# Quality of the science should include:

- Background, scientific merit, and impact of the project
- Potential of the project to generate new knowledge and lead to additional research projects

#### Quality of the research plan should include clear statements of:

- Hypotheses and aims/objectives of the proposed research. Applicants should work with the ATHN Administrator at their site to review the "ATHN Research Report Brief" which contains the number and type of core and non-core data elements in the ATHNdataset as captured within the ATHN Systems. <u>Applicants should clearly explain how their project will use the ATHNdataset and what data elements will be analyzed.</u> Please note that the use of other databases is not allowed. Any application proposing to use data collection system other than ATHN Systems will be deemed ineligible.
- Study design and methodology; the project method and design should be appropriate to test proposed hypotheses
- Feasibility analysis
- Potential limitations and how to address them
- Future studies to be pursued if specific aims are accomplished

- Statistical plan and/or considerations. Patient or sample numbers and statistical methods should be identified.
- Plan for obtaining statistical support. Applicants may request consultation up to 5 hours at no cost from ATHN prior to submission of the pre and full proposal to assist with planning to implement the statistical portion of their project.
- Applicants may request the support services of an ATHN biostatistician during the duration of the funded project and there is a cost for such consultation. If this service is anticipated, the rationale for and percent effort allotted for the biostatistician must be sufficiently explained in the full proposal narrative and the expense must be reflected in the full proposal budget. Invited full proposal applicants must contact ATHN at <a href="mailto:support@athn.org">support@athn.org</a> to request assistance in determining the number of hours of consultation needed and the associated cost. Requests must be made by June 1, 2024.
- Human subject protections should be appropriately described, if applicable.
- A project timeline. Applicants should specify what will be accomplished in Year One versus what will be accomplished in Year Two. Applicants should note that the contracting process timeline should be incorporated into their schedule.
- Role and Benefit of the ATHNdataset should include:
  - Clear explanation of how the ATHNdataset will be used to address objectives. This is a critical part of the application.
  - Listing of specific core data elements used in the study (a comprehensive list of core data elements appears on the last page of this RFP).
- 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.
- 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 site, the mentor should describe evidence of an appropriate communication and collaboration plan.
- e. Explanation of the way the mentor has mentored applicant in the past and the plan for mentoring to improve the scientific writing.
- f. 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.
- g. 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.

# 7. Project Budget and Addendum to Budget.

Each full proposal must include a comprehensive budget. The expenses below are permitted by HTRS/ATHN as part of the project budget, which may not exceed a total of \$100,000 USD for a 24-month award. Full Proposal applicants are required to use the budget template provided by HTRS/ATHN.

# **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
- Up to \$1,000 of the direct costs of the project budget may be earmarked to support travel expenses for the applicant to attend the annual ATHN Data Summit and or the biennial HTRS Scientific Symposium 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.)
- Consultant costs for biostatistical consultation, statistical or data management support

Collaborating site (s) costs if proposed

Indirect Costs/Facilities and Administrative Costs of up to 8% of the direct costs not to exceed \$7,408 USD 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 \$100,000 USD for a 24-month award.

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

- An explanation and justification of each line item requested in the budget template.
- 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.
- A brief discussion of alternatives if this additional funding is not secured.

# **Notification of Grant Awards**

Notification of final award decisions will be made in August 2024.

Questions about the preparation and submission of 2024 DREAM Award pre-proposals and invited full proposals can be directed to <a href="mailto:support@athn.org">support@athn.org</a>.

The ATHNdataset is a de-identified data set defined by Expert Determination under section 164.514(b)(l) of the HIPAA Privacy Rule. The ATHNdataset Core Data Elements may change over time.

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# **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
	Sex assigned at Birth
	Gender Identity
	Identifies as Transgender
	Race
	Ethnicity
	Education Level
	Employment Level
	Zip Code
Authorizations	ATHNdataset Patient Authorization
Insurance Information	Category
	Start Date
	Payer Name
	Туре
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
	Target Joint History
	00///0.10
	COVID-19
Surgeries/Procedures	Date

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

The ATHNdataset is a de-identified dataset defined by Expert Determination under section 164.514(b)(1) of the HIPAA Privacy Rule. The ATHNdataset Core Data Elements may change over time. Data contributed to the ATHNdataset is made available by ATHN to approved collaborators to support clinical care and outcomes analysis, research, advocacy, and public health reporting in communities impacted by hematologic disorders.



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Version 4.0 - August, 2021