**Program Announcement for the Defense Health Agency**

# Bone Marrow Failure Research Program
# Investigator-Initiated Research Award

Funding Opportunity Number: HT942526BMFRPIIRA

Pre-Application Due: August 5, 2026

Application Due: November 4, 2026

***This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.***

# Content

## Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

## Who to Contact for Support

**eBRAP Help Desk**

301-682-5507
help@eBRAP.org

*Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.*

**Grants.gov Support Center**

800-518-4726
International: 1-606-545-5035
support@grants.gov

*Questions regarding Grants.gov registration and Workspace.*

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

***Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).***

# 1. Basic Information About the Funding Opportunity

**Summary:** Supports studies that further develop mature ideas, expand upon key discoveries, and have the potential to make significant advances in bone marrow (BMF) failure research and/or patient care. Investigator-Initiated Research Award (IIRA) applications may involve translational and clinical research including studies in preclinical models, research with human data and/or anatomical substances, and research with human subjects, as well as correlative studies associated with a clinical trial(s); however, **this award mechanism does not support clinical trials**. IIRA applications may also support Investigational New Drug (IND)-enabling efforts such as lead compound characterization, and assessments of formulation and stability, absorption, distribution, metabolism and excretion, dose/response and toxicology.

**Distinctive Features:**

- **This funding mechanism allows for a partnering Principal Investigator (PI).** Only the initiating PI will submit a pre-application, but both PIs will need to submit full applications. The partnering PI application is an abbreviated package specific to their distinct portion of the research project. Be advised, all associated applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.
- **This award mechanism requires preliminary data relevant to the proposed project.** Applications can support clinical research studies; however, this mechanism does not allow clinical trials.

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $1.25M to fund approximately one Investigator-Initiated Research Award application with total cost caps of $1.25M per award. The maximum period of performance is 3 years. It is anticipated that awards made from this fiscal year 2026 (FY26) funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

## Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), August 5, 2026
- **Invitation to Submit an Application:** September 16, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, November 4, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, November 12, 2026
- **Peer Review:** January 2027
- **Programmatic Review:** March 2026

**Announcement Type:** Initial

**Funding Opportunity Number:** HT942526BMFRPIIRA

**Assistance Listing Number:** 12.420

# 2. Eligibility Information

## 2.1. Eligible Applicants

### 2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

### 2.1.2. Principal Investigator

Independent investigators at all career levels affiliated with an eligible organization are eligible to be named PI or partnering PI on the application, regardless of ethnicity, nationality or citizenship status.

An investigator may be named as a PI on a maximum of two applications to this program announcement. If an investigator is named as a PI on more than two BMFRP IIRA applications, only the first two applications received will be accepted; additional applications will be administratively withdrawn.

## 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

## 2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

# 3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the Bone Marrow Failure Research Program (BMFRP). The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the BMFRP in 2008 to provide support for research that has high potential impact and exceptional scientific merit in bone marrow failure. Appropriations for the BMFRP from FY08 through FY24 totaled $71.55 million (M). The FY26 appropriation is $7.50M.

The vision of the BMFRP is to understand and cure BMF diseases. The program challenges the scientific community to design innovative research of inherited and acquired BMF diseases to improve understanding of the pathobiology and advance prevention and treatment. Through these efforts, the BMFRP seeks to improve the health of affected Service Members, Veterans and the general public, with the ultimate goal of cure.

**BMFRP Objective**

**The BMFRP objective** is to fund research in the areas of inherited or acquired BMF. Studies focused on BMF syndromes and their progression to other malignancies, such as leukemia, are acceptable. ***However, the BMFRP will not consider research with a primary focus on myeloproliferative neoplasms, leukemia or other malignancies.*** *Applications proposing stem cell biology studies and translational projects, including bone marrow transplantation studies and cellular therapies, should clearly relate to BMF diseases.*

*Projects related to **Graft Versus Host Disease (GVHD)** must explain how the issues the proposed research is investigating **are specifically relevant to BMF**, but not other stem cell transplant patients. Applications should describe the experimental design **for using BMF models** to directly test the proposed hypotheses. The BMFRP will not consider GVHD studies in other hematological disorders.*

The BMFRP encourages research that improves the understanding and treatment of BMF diseases and conditions. To assist the application review process, applicants **must** specify the type(s) of disease or condition that will be the primary focus of the investigation. The following is a non-exhaustive list of diseases and conditions that are relevant to the objective of the BMFRP:

- Aplastic Anemia
- Diamond-Blackfan Anemia
- Dyskeratosis Congenita/Telomere Biology Disorders
- Fanconi Anemia
- GATA2 Deficiency
- Induced BMF: Radiation/Chemical
- Myelodysplastic Syndromes
- Paroxysmal Nocturnal Hemoglobinuria
- Pearson Syndrome
- SAMD9/SAMD9L Germline Mutations
- Severe Congenital Neutropenia
- Shwachman-Diamond Syndrome
- VEXAS Syndrome
- Adenosine Deaminase 2 Deficiency

If the proposed research project focuses on a disease that is not listed, the application should clearly identify the disease or condition that is central to the study and provide justification that

the proposed research project meets the objective of the BMFRP. If the proposed research project is not specific for one disease or condition and will address multiple diseases or conditions, the application should clearly articulate the BMF communities that will benefit from the study.

## 3.1. Award History

The Investigator-Initiated Research Award mechanism was first offered in FY21. Since then, 38 Investigator-Initiated Research Award applications were received, and eight were recommended for funding.

## 3.2. Intent of the Investigator-Initiated Research Award

The BMFRP Investigator-Initiated Research Award (IIRA) is intended to support studies that further develop mature ideas, expand upon key discoveries, and advance research or patient care for individuals affected by BMF diseases. Applications may include translational and clinical research, such as studies in animal models, research using human data or anatomical substances, research involving human subjects, correlative studies linked to clinical trials, and Investigational New Drug (IND)-enabling efforts. However, ***this award does not support clinical trials.***

Applications proposing correlative studies must have ***an associated clinical trial(s) with approval from relevant regulatory and ethical bodies and actively recruiting participants at the time of full application submission.*** The correlative research should address critical knowledge gaps, validate key findings, expand on transformative results or achieve other impactful outcomes.

For IND-enabling efforts, the research should focus on empirical, product-driven studies to generate data required for IND applications to the U.S. Food and Drug Administration (FDA). This includes lead compound characterization, formulation and stability, absorption, distribution, metabolism, excretion, dose/response and toxicology.

***Applications must include preliminary and/or published data that are relevant to BMF and the proposed research project.***

### 3.2.1. Focus Areas for the IIRA

To meet the intent of the funding opportunity, applications **must** address at least one of the FY26 BMFRP focus areas listed below.

- Find effective BMF treatments and cures
- Understand the causes and progression of BMF diseases

### 3.2.2. Key Elements for the IIRA

The following are significant features of this award mechanism:

- **Impact:** Proposed research projects should address a central critical issue or question in BMF disease research or patient care. High-impact research, if successful, will significantly advance current methods and concepts for the prevention, detection, diagnosis and/or treatment of BMF diseases.
- **Translational Potential:** The application should consider and describe the translational potential of the proposed project. The proposed study should support the reciprocal transfer

of information between basic and clinical science to further develop mature ideas and expand upon key discoveries. Applications should address how the research will translate findings into an understanding of causes or progression of BMF diseases, or strategies for treatment and/or a cure.

- **Preliminary Data:** Applications may derive observations driving the proposed research idea from laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients or anecdotal data. Applications must include preliminary and/or published data that are relevant to the mission of the BMFRP and support the proposed research project. Any unpublished preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team.
- **Multidisciplinary Collaborations:** The IIRA encourages applications with multidisciplinary team of investigators who bring specific skills that contribute to the successful completion of the project. This can include both intellectual input and research resources (e.g., supplies, reagents, equipment, personnel, services, tissue samples, access to patients or populations).
- **Correlative Studies:** The IIRA encourages applications proposing correlative studies of clinical trials to better characterize treatment response, validate key research results, expand upon potentially game-changing results or provide insights into disease biology, treatment mechanisms or other disease-related complications. ***The associated clinical trial(s) should be actively recruiting participants at the time of full application submission.***
- **IND-enabling Studies:** Applications may propose studies that will enable empirical, product-driven, and focused accumulation of data to support an IND application to the U.S. Food and Drug Administration (FDA).
- **Partnering PI Option:** The IIRA encourages applications that include meaningful and productive collaborations between investigators and includes an option for more than one PI. Electing to submit to the Partnering PI Option does not affect the total cost limit. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to Section 5.3, Submission Instructions.

### 3.2.3. Other Important Considerations for the IIRA

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

**Clinical trials are not allowed within this funding opportunity.**

***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research*, which is allowed.**

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

Applications from investigators within the DOW and applications involving multidisciplinary collaborations among academia, industry, the DOW, the U.S. Department of Veterans Affairs (VA) and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, their Families and the American Public. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

## 3.3. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

## 3.4. Funding Details

**Period of Performance:** The maximum period of performance is **3** years.

**Cost Cap:**

The application's total costs budgeted for the entire period of performance should not exceed **$1.25M** for single PI applications. For partnering PI applications, the combined total costs budgeted for the Initiating PI and Partnering PI should not exceed **$1.25M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

The appropriateness of the budget for the proposed research will be assessed during peer review.

**For Partnering PI Applications:**

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

**Direct Cost Restrictions:** For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for two investigators to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the BMFRP IIRA.
- Costs for correlative studies associated with a clinical trial(s), if applicable.

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Clinical Trial Costs.

# 4. Application Contents and Format

## 4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

***Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.***

***Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.***

## 4.2. Pre-Application Components

Pre-application submissions must include the following components.

The PI (Single PI application) or Initiating PI (Partnering PI application) must submit the following pre-application components.

***Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.***

- **Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Objective:** Describe how the proposed research adheres to the intent of the FY26 BMFRP Objective. Identify the relevant BMF disease or condition and FY26 BMFRP Focus Area(s) it seeks to address.
  - **Background/Research Problem:** State the background and scientific rationale on which the proposed research project is based. Applications must include relevant literature citations and preliminary data. Clearly articulate how the research addresses a critical problem or question in BMF diseases. If proposing an IND-enabling study, identify the lead therapeutic candidate(s) and briefly justify readiness for the proposed IND-enabling effort.
  - **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the anticipated scientific approach. Include a description of controls, as appropriate.
    - For project proposing correlative studies associated with clinical trial(s):
      - Specify how the proposed project complements or extends the existing research efforts.
      - Explain how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-changing results,

or provides insights into disease biology, treatment mechanisms or other disease-related complications.

- ***Ensure that the associated clinical trial(s) will be active at the time of full application submission.***

- **Impact:** Explain the potential near- and long-term impact of the proposed research project and how it will move the research field toward achieving the BMFRP's vision to understand and cure BMF diseases.
- **Personnel:** Concisely describe how the research team's combined expertise will better address the research question and lead to successful completion of the proposed research

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title and reference source, including volume, chapter, page numbers and publisher, as appropriate).
  - **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms and symbols used in the Preproposal Narrative.
  - **Key Personnel Biographical Sketches:** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications and previous work accomplished.

## 4.3. Full Application Components for the PI or Initiating PI

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected**.**

**Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

### 4.3.1. Full Application Components for the Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

**(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:**

***IMPORTANT:*** *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

**(b) Attachments:**

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (12-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below.

  - **Background:** Present the ideas and reasoning behind the proposed research project and clearly demonstrate that there is sufficient scientific evidence to support the proposed stage of research, including preliminary, published and/or unpublished data. Cite relevant literature.
    - For IND-enabling studies, identify the lead therapeutic candidate(s) that are to be characterized in support of an IND application filing. Details for each lead therapeutic candidate should be described in Attachment 11: Lead Therapeutic Candidate(s) Statement.
  - **Objective:** State the objectives of the study. State the FY26 BMFRP Focus Area(s) to be addressed by the proposed research.
  - **Specific Aims:** Concisely explain the project's specific aims. The aims should agree with the primary aims and associated tasks described in the SOW (Attachment 5). If this research project is part of a larger study, present only the tasks that this award would fund.
  - **Research Strategy:**
    - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
    - Address potential problem areas and pitfalls, and present alternative methods and approaches.
    - If applicable, briefly describe the relevance of the chosen animal model to the BMF disease under investigation; full details will be required in the Animal Research Plan (Attachment 10).
    - If human subjects, anatomical samples or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data.
    - For all applications proposing clinical research describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2).
    - If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to

access and publish data. Refer to the General Application Instructions, Appendix 4, for additional considerations.

- If an IND-enabling study is proposed, describe how the data reporting and documentation are appropriate for a regulatory filing with the FDA, or international regulatory agency, if applicable.

– **Correlative Study (if applicable):**

- Describe the clinical trial(s) the proposed study will correlate to and provide the clinicaltrials.gov ID number(s). Provide evidence that the associated clinical trial(s) will be active at the time of full application submission.
- Specify how the proposed correlative study complements or extends the existing efforts and explain how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-changing results or provides insights into disease biology, treatment mechanisms or other disease-related complications.
- If the lead investigator of the clinical trial(s) is not the named PI or key personnel on this application, provide evidence of collaboration with the lead investigator of the clinical trial(s) and demonstrate access to the relevant patients, patient biological samples, patient data or other patient resources necessary to conduct the proposed correlative study.
- Describe the outcome measures to be captured and plans for data analysis.

– **Statistical Plan:** Clearly describe the statistical plan and rationale for the statistical methodology and explain how it is appropriate for the proposed study. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, as applicable. Include any plans for blinding and randomization.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

***There are no page limits for these components unless otherwise noted. Include only components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.***

– **References Cited:** List the references cited in the Project Narrative using a standard reference format (include URLs, if available).

– **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms and symbols.

– **Facilities, Existing Equipment and Other Resources:** Describe the facilities and equipment available for performance of the proposed project; include any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized form for this information.

– **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meets the eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Letters of Access *(if applicable)*:** If access to patients, patient samples, patient datasets or other resources is necessary to conduct the study, and the PI or key personnel on this application does not own the resource, provide a letter of support signed by the appropriate authorizing individual confirming access to the resource.
- **Intellectual Property:** Information can be found in the Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."
  - **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Inclusion Enrollment Report *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the "Public Health Service (PHS) Inclusion Enrollment Report", a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race and ethnicity. Studies utilizing human biospecimens/datasets or resources that cannot be linked to a specific individual, ethnicity or race (typically classified as exempt from IRB review) are exempt from this requirement. If an application is adding an aim to conduct biosample collection and biomarker analysis to an existing clinical trial that is supported by a different source of funding, use of the patients enrolled in that trial is expected and the study potentially may not include diverse populations. These applications are exempt from this requirement.
- **Sex as a Biological Variable Strategy (two-page limit is recommended):** Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **Research Sharing Plan:** Describe the type of data or research resources (e.g., bio-specimen, analysis tool/software, training material) to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical research participants. Include the name of the repository(ies) where scientific data and resources arising from the proposed study

will be archived, if applicable. Identify and provide the rationale for any data or resources that will not be shared (e.g. for intellectual property, feasibility, cost or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

***Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan which will be requested only after a recommendation for funding is made.***

Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

  Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project. Include sufficient scientific evidence to support the proposed stage of research. If proposing a correlative study to a clinical trial(s), provide the clinicaltrials.gov ID number(s). If proposing an IND-enabling effort, identify the lead therapeutic candidate(s) that is to be studied in support of an IND application filing.
  - **Objective:** State the overall objective of the study.
  - **Focus Area:** State the FY26 BMFRP Focus Area(s) to be addressed by the proposed research.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design, including appropriate controls.
  - **Impact:** Summarize how the proposed project is relevant to and will have near- and long-term impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be impacted by the research.
  - **Military Relevance:** Describe how the study is relevant to military health, if applicable.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - State the FY26 BMFRP Focus Area(s) to be addressed by the proposed research.
  - Describe the objectives and rationale for the proposed research***.***
    - Describe the ultimate applicability of the research.

        - What bone marrow disease/syndrome is the study seeking to address and how will it help?
        - What are the potential clinical applications, benefits and risks?
    - If the research is too early for immediate clinical applicability, then describe the interim outcomes.
    - What are the likely contributions of the proposed research project to advancing the field of BMF research and/or patient care among those with BMF diseases/syndromes?
        - What is the projected time it may take to achieve a person-related outcome?
    - Identify the lead therapeutic candidate(s) that is to be studied in support of an IND application filing, if applicable.

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to either the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work or Example: Assembling a Generic Statement of Work, whichever is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

  ***Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.***

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf"**. ***The impact statement should be written with a broad audience in mind, including readers without a background in science or medicine.***
    - Describe how the proposed research project addresses the FY26 BMFRP Focus Area(s) and is important to understanding the causes and progression of BMF diseases, realizing improvements in patient care and/or finding a cure.
    - Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will directly result from the proposed research and explain how the outcomes will drive the BMF field forward and support new avenues for research or clinical care.
    - Describe the long-term impact: Explain the potential long-term impact of this study on the field of BMF disease research and/or patient care.
    - If applicable, describe how the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Attachment 7: Translation Potential Statement (one-page limit): Upload as "Translation.pdf".**
    - Describe how the project is expected to translate promising research findings into advances in the understanding of BMF diseases or strategies for prevention and/or a cure and provide an anticipated timeline
    - Explain how the proposed study will support the reciprocal transfer of information between basic and clinical science.
    - Include a description of the next steps in the translation of the results of this research after the end of the project.

- Include a brief description of any collaborations with clinicians or physician-scientists for the proposed study. Describe how the research team will leverage these relationships to ensure potential translation of study finding in the future.

- **Attachment 8: Transition Plan (three-page limit): Upload as "Transition.pdf".**
  - Describe/discuss the methods and strategies proposed to move the product to the next phase of development or delivery to the military or civilian market after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. The Transition Plan attachment should include the components listed below.
  - Details of the strategy, schedule and milestones to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be pursued). Include a description of collaborations and other resources that will be used to provide continuity of development.
  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the FDA regulatory strategy, to include considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice and Good Clinical Practice guidelines, if appropriate.
  - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures and other clinical support tools, scientific journal publications, models, simulations and applications. A "knowledge product" is a non-materiel product that addresses an identified need or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools or to support materiel solutions (systems to develop, acquire, provide and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.
  - A schedule and milestones for transitioning the technology or knowledge product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice or approval by the FDA). Include identification of the FDA regulatory strategy (if appropriate).
  - Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.
  - A risk analysis for cost, schedule, manufacturability and sustainability.

- **Attachment 9: Research Team Statement (one-page limit): Upload as "Team.pdf".** Discuss the qualifications of the research team and each individual's specific contributions to the project, including how the appropriate experience is incorporated to address the research question and enable the success of the proposed project. Clearly state whether key personnel are not receiving salary from the award. If applicable, provide assurances/letters of commitment that the unpaid personnel will contribute the required level of effort to complete the project. Describe the PI's record of accomplishment and their ability to lead the research team to accomplish the proposed research project. Describe previous experience most pertinent to this project.

***If submitting under the Partnering PI Option***, describe how the partners' combined experience will better address the research question and explain why the work should be done together rather than through separate efforts. Describe plans for effective collaboration and communication throughout the project.

- **Attachment 10: Animal Research Plan (three-page limit): Upload as "AnimalResPlan.pdf"**. ***(Attachment 10 is only applicable and required for applications proposing animal studies.)***

  If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the IACUC. The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis and identification of the primary endpoint(s).

- **Attachment 11: Lead Therapeutic Candidate(s) Statement, if applicable (six-page limit): Upload as "Lead.pdf".** Provide the background information supporting the validation and further characterization of a proposed lead therapeutic candidate(s) as a viable therapeutic approach. Explain how the proposed study is empirical in nature and product-driven.

  - Provide the chemical (or biological) identities of the lead molecule(s) or limited group of specific compounds.
  - Provide proof of identity and purity of the lead(s). For small molecules, typically >95% by nuclear magnetic resonance, liquid chromatography-mass spectrometry (LC-MS), melting point, etc., with no single impurity >0.5%. For biologics, often by high-performance liquid chromatography, LC-MS, immunochemistry, nucleotide or amino acid sequence analysis, etc.
  - If applicable, provide data on primary and secondary in vitro bioactivity studies used for optimization or structure-activity relationships.
  - Describe the putative mechanism of action. Provide data to support target selectivity, engagement and desirable activity at the intended target.

  - Provide proof-of-concept efficacy data in at least two preclinical model systems of BMF, including whole animal and cellular model systems.

- **Attachment 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

**(c) Additional Application Materials:**

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov eBRAP.org

**i. Research & Related Senior/Key Person Profile (Expanded)**

- **Biographical Sketch**
- **Current/Pending Support**

  *Intragovernmental applicants must include their internally supported research and development programs.*

**ii. Research & Related Budget**

*Partnering PI Option (PPIO): Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s), or vice versa, even if they are located within the same organization. Refer to **Section 3.4, Funding Details**, for detailed budget information.*

**iii. Project/Performance Site Location(s)**

**iv. Research & Related Subaward Budget Attachment(s)** *(if applicable, Grants.gov submissions only)*

### 4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

**(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov Submissions Only)*:**

**(b) Attachments:**

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 12: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 13: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

**(c) Additional Application Materials:**

The following are additional forms for application submission. Follow the instructions specific to the submission portal found within the GAI.

| Grants.gov | eBRAP.org |
|---|---|

**i. Research & Related Senior/Key Person Profile (Expanded)**

- **Biographical Sketch**
- **Current/Pending Support**

  *Intragovernmental applicants must include their internally supported research and development programs.*

**ii. Research & Related Budget**

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI(s) should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed budget information.*

**iii. Project/Performance Site Location(s) Form**

**iv. Research & Related Subaward Budget Attachment(s) Form** *(if applicable, Grants.gov submissions only)*

## 4.4. Other Application Elements

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

# 5. Submission Requirements

## 5.1. Location of Application Package

Download the application package components for HT942526BMFRPIIRA from Grants.gov or eBRAP, depending on which submission portal will be used.

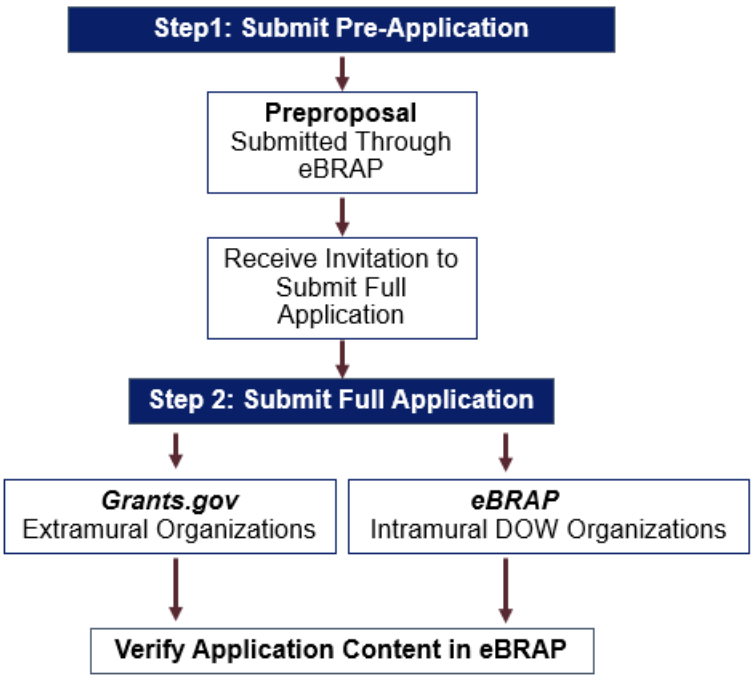
## 5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

## 5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

***Application Submission Workflow***




### 5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting the PPIO.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP. Contact the eBRAP Help Desk if any changes need to be made.

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

| Application Includes: | Select Mechanism Option: |
|---|---|
| **Single Investigator** | Investigator-Initiated Research Award (IIRA) |
| **Partnering Investigators** | Investigator-Initiated Research Award – Partnering PI Option (IIRA-PPIO) |

**PPIO:** After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

***Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI.*** Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.
- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.

### 5.3.2. Full Application Submission

**Grants.gov Submissions:** Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

**eBRAP Submissions:** Only intramural DOW organizations may submit full applications through eBRAP.

### 5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

## 5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

## 5.5. Intergovernmental Review

Not applicable for this funding opportunity.

# 6. Application Review Information

## 6.1. Application Compliance Review

***Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).***

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal.

Members of the FY26 BMFRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 BMFRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

## 6.2. Review Criteria

### 6.2.1. Pre-Application Screening Criteria

To determine the merits of the pre-application and the relevance to the mission of the BMFRP, pre-applications will be screened based on the following criteria:

- **Objective:** How well the proposed research adheres to the intent of the FY26 BMFRP award mechanism. Whether the proposed research addresses at least one of the FY26 BMFRP Focus Area(s).
- **Background/Research Problem:** How well the background, scientific rationale, preliminary data and/or relevant literature citations demonstrate sufficient evidence to support the proposed research project. To what degree does the research address a critical problem or question in BMF disease. If applicable, the degree to which the proposed lead candidate(s) is ready for the IND-enabling study.

  **Specific Aims and Study Design:** How well the outlined research project states and addresses the specific aims. How well the anticipated scientific approach (including controls) supports the evaluation of the specific aims proposed.

  If a correlative study to an existing clinical trial(s), how well it complements or extends the existing research efforts and explains how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-

changing results or provides insights into disease biology, treatment mechanisms or other disease-related complications.

- **Impact:** To what degree the proposed research will make important near- and long-term contributions that significantly advances the research field toward the BMFRP's vision of understanding and curing BMF diseases.
- **Personnel:** To what degree the PI(s) and research team's backgrounds and BMF disease-related expertise are appropriate to successfully carry out the proposed research project.

### 6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, which are of equal importance.

- **Research Strategy and Feasibility**
  - How clearly the ideas and reasoning behind the proposed research project demonstrate sufficient scientific evidence, including preliminary data, to support moving into the proposed stage of research.
  - How well-developed and feasible the proposed research aims, experimental design, methods and analysis support the research objectives.
  - How thoroughly the application acknowledges potential problems or pitfalls and addresses alternative approaches.
  - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
  - If applicable, how well-established the human subject recruitment, data or sample acquisition plans are to achieve the study objectives.
  - If applicable, whether a strategy for the inclusion of women and minorities appropriate to the objectives of the study was included and to what degree the rationale supports the composition of the proposed study population in terms of sex, racial and ethnic group.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study or whether the justification for a single-sex study is sufficiently strong.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or an international regulatory agency.
- **Correlative Study (if applicable)**
  - Whether the associated clinical trial(s) is described in sufficient detail to assess the relevance and appropriateness of the proposed correlative study.
  - How well the proposed correlative study complements or extends the existing research efforts and provides additional relevant insight beyond the clinical trial(s) itself and will advance the characterization of treatment response, validate key research results, expand upon potentially game-changing results or provides insights into disease biology, treatment mechanisms or other disease-related complications.

- Whether there is sufficient evidence of collaboration with the lead investigator of the associated clinical trial(s), or that the PI or key investigator of this application is also the lead investigator of the associated clinical trial(s).
- Whether the application demonstrated access to relevant patients, patient biological samples, patient data or other patient resources necessary to conduct the proposed correlative study.
- Whether the application sufficiently describes appropriate outcome measures and data analyses for the proposed correlative study.

- **Statistical Plan**
  - To what degree the statistical plan is appropriate for the proposed project, including any plans for blinding and randomization, as applicable.
  - How well the proposed sample size and the method by which it was derived, including power analysis calculation, are appropriate, as applicable.
- **Impact**
  - How well the research project addresses FY26 BMFRP Focus Area(s) and, if successful, will make important contributions towards understanding the causes and progression of BMF diseases, realizing improvements in patient care and/or finding a cure.
  - To what degree the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) will drive the BMF field forward and support new avenues for research or clinical care.
  - How well the anticipated long-term gains from this research will yield relevant results for BMF disease research or patient care.
  - If applicable, to what extent the anticipated outcomes of the proposed study will make an impact in understanding health differences between sexes.
- **Translation Potential**
  - How well the project will translate promising research findings into advances in the understanding of BMF diseases or strategies for prevention and/or a cure.
  - Whether the proposed study will support the reciprocal transfer of information between basic and clinical science.
  - How well the next steps to be taken to translate study results following the completion of the proposed study are described.
  - To what degree collaborations with clinicians or physician-scientists will be leveraged to ensure potential translation of study findings in the future.
- **Transition Plan**
  - Whether the schedule and milestones for bringing the product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice or approval by the FDA) are achievable.
  - Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.

- How the regulatory strategy and the development plan to support the planned product label, if applicable, are appropriate and well-described.
- Whether the risk analysis for cost, schedule, manufacturability and sustainability is realistic and reasonable.
- How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Research Team**
  - How qualified the research team is to conduct the proposed research including how well each member's experience is incorporated into the project to address the research question and ensure success. To what extent the background and experience of the PI and key personnel are appropriate to accomplish the proposed research project.
  - To what extent the levels of effort by the PI and key personnel are appropriate to ensure the success of this project.
  - How well the PI's record of accomplishments demonstrates their ability to lead the research team to accomplish the proposed research project**.**

  ***For PPIO applications only:***
  - How the partners' combined expertise will better address the research question.
  - How well the plans for collaboration and communication throughout the project are described and will be sufficient to facilitate a successful research project.
- **Lead Therapeutic Candidate (if applicable)**
  - Whether an appropriate lead therapeutic candidate(s) has been identified for further characterization.
  - How strongly the background supports the applicant's reasoning that the proposed therapeutic approach is viable for clinical application.
  - To what extent the study is empirical in nature and product-driven.
  - To what degree the data shows selectivity and engagement for an intended target and elicits a desired activity.
  - How well the preliminary data support validation of an identified bioactive compound or group of lead compounds with demonstrated efficacy in at least two BMF-relevant model systems.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable and includes dissemination to affected communities, study participants and/or the scientific community. If applicable, whether a specific repository(ies) is named where data and research resources arising from the project will be stored.

- **Budget**
  - Whether the **total** costs exceed the allowable total costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Environment**
  - Whether the scientific environment is appropriate for the proposed research.
  - Whether the research requirements are supported by the availability of, and accessibility to, facilities and resources (including collaborative arrangements).
  - Whether the quality and extent of institutional support are appropriate for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
  - To what extent the writing, clarity and presentation of the application components influence the review.

### 6.2.3. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of peer reviewers
- Relevance to the priorities of the FY26 BMFRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Translation potential

## 6.3. Application Review and Selection Process

### 6.3.1. Pre-Application

Following the pre-application screening, PIs (Single PI applications) or Initiating PIs (Partnering PI applications) will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information About the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

### 6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria

to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are subject to review and approval by a designated official. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds.

## 6.4. Risk, Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in the 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the SAM.

An applicant organization may review the SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

# 7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the BMFRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website. After all awards are made, the CDMRP includes individual award information in a searchable database.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

***Only an appointed DHACA Grants Officer may obligate the government to the expenditure of funds to an extramural organization.*** No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

***Intragovernmental obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.***

Funding obligated to ***intragovernmental and intramural DOW organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD) or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOW investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award.

# 8. Post-Award Requirements

## 8.1. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

The GAI contain information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

***If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.***

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review.

## 8.2. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical progress reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

PHS Inclusion Enrollment Reporting (Required for research proposing clinical research): Enrollment reporting on the basis of sex, race and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on eBRAP.

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil and administrative proceedings as specified in the applicable Representations.

## 8.3. Additional Requirements

Unless otherwise restricted, changes in the PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

PPIO: An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

An organizational transfer of an award will not be allowed in the last year of the original period of performance or any extension thereof.

# 9. Other Information

## 9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01d.

## 9.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

### 9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the full application:

- The Project Narrative is missing.
- The Budget is missing.
- Submission of an application for which a letter of invitation was not issued.
- Translation Potential Statement is missing.
- Transition Plan is missing.

### 9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

### 9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY26 BMFRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.

- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- The invited application proposes a different research project than that described in the pre-application.
- The application does not address at least one of the FY26 BMFRP Focus Area(s).
- A clinical trial is proposed.
- If an investigator is named as a PI on more than two BMFRP IIRA applications, only the first two applications received will be accepted; additional applications will be administratively withdrawn

### 9.2.4. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the DHACA Grants Officer for a determination of the final disposition of the application.

# Appendix 1. Full Application Submission Checklist

| Full Application Components | Uploaded | |
|---|---|---|
| | Initiating PI | Partnering PI |
| **SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*** | ☐ | ☐ |
| **Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP submissions only)*** | ☐ | ☐ |
| **Attachments** | | |
| **Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"** | ☐ | |
| **Supporting Documentation – Attachment 2, upload as "Support.pdf"** | ☐ | |
| **Technical Abstract – Attachment 3, upload as "TechAbs.pdf"** | ☐ | |
| **Lay Abstract – Attachment 4, upload as "LayAbs.pdf"** | ☐ | |
| **Statement of Work – Attachment 5, upload as "SOW.pdf"** | ☐ | ☐ |
| **Impact Statement – Attachment 6, upload as "Impact.pdf"** | ☐ | |
| **Translation Potential Statement – Attachment 7, upload as "Translation.pdf"** | ☐ | |
| **Transition Plan – Attachment 8, upload as "Transition.pdf"** | ☐ | |
| **Research Team Statement – Attachment 9, upload as "Team.pdf"** | ☐ | |
| **Animal Research Plan – Attachment 10, upload as "AnimalResPlan.pdf"** | ☐ | |
| **Lead Therapeutic Candidate(s) Statement – Attachment 11, upload as "Lead.pdf"** | ☐ | |
| **Representations *(Grants.gov submissions only)* – Attachment 12, upload as "RequiredReps.pdf"** | ☐ | ☐ |
| **Suggested Intragovernmental Budget Form *(if applicable)* – Attachment 13, upload as "IGBudget.pdf"** | ☐ | ☐ |
| **Additional Application Materials** | | |
| **Research & Related Senior/Key Person Profile (Expanded)** | ☐ | ☐ |
| **Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)** | ☐ | ☐ |
| **Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)** | ☐ | ☐ |
| **Research & Related Budget** | ☐ | ☐ |
| **Project/Performance Site Location(s)** | ☐ | ☐ |
| **Research & Related Subaward Budget Attachment(s) (*if applicable*)** | ☐ | ☐ |
| **Confidential Letters of Recommendation** | ☐ | ☐ |

# Appendix 2. Acronym List

| | |
|---|---|
| BMFRP | Bone Marrow Failure Research Program |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| DHA | Defense Health Agency |
| DHA R&D | Defense Health Agency Research and Development |
| DHACA | Defense Health Agency Contracting Activity |
| DOD | U.S. Department of Defense |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DOW | U.S. Department of War |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FDA | U.S. Food and Drug Administration |
| FY | Fiscal Year |
| IACUC | Institutional Animal Care and Use Committee |
| IIRA | Investigator-Initiated Research Award |
| IRB | Institutional Review Board |
| LC-MS | Liquid Chromatography-Mass Spectrometry |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NIH | National Institutes of Health |
| ORRC | Office of Research and Regulatory Compliance |
| PDF | Portable Document Format |
| PHS | Public Health Service |
| PI | Principal Investigator |
| PPIO | Partnering Principal Investigator Option |
| R&D | Research and Development |
| RPPR | Research Performance Progress Report |
| SABV | Sex as a Biological Variable |
| SAM | System for Award Management |
| SF424 R&R | Standard Form 424 (Application for Federal Assistance, Research & Related) |
| SOW | Statement of Work |
| UEI | Unique Entity Identifier |

| | |
|---|---|
| URL | Uniform Resource Locator |
| USC | United States Code |
| VA | U.S. Department of Veterans Affairs |