I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-BMFRP-IDA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 21, 2023
- **Invitation to Submit an Application:** July 26, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, September 20, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, September 25, 2023
- **Peer Review:** November 2023
- **Programmatic Review:** January 2024

This program announcement must be read in conjunction with the General Application Instructions, version 803. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) Bone Marrow Failure Research Program (BMFRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The BMFRP was initiated in FY08 to provide support for research of exceptional scientific merit. Appropriations for the BMFRP from FY08 through FY22 totaled $56.55 million (M). The FY23 appropriation is $7.5M.

The vision of the BMFRP is to understand and cure bone marrow failure (BMF) diseases. Toward that end, the program challenges the scientific community to design innovative research approaches based on sound scientific evidence that will advance the understanding and treatment of inherited and acquired BMF diseases to improve the health of affected Service Members, Veterans, and the general public, with the ultimate goals of prevention and cure.

The objective of the FY23 BMFRP is to fund research in the areas of congenital or acquired BMF. Studies focused on BMF syndromes and their progression to other malignancies, such as leukemia, are acceptable. ***However, research primarily focused on myeloproliferative neoplasms, leukemia, or other malignancies will not be considered.*** Stem cell biology studies and translational projects, including bone marrow transplantation studies and cellular therapies, should be clearly related to BMF diseases.

*Projects related to **Graft versus Host Disease** (GVHD) must both **explain the rationale** for why the issues being investigated are specifically relevant to patients with BMF, but not other stem cell transplant patients, and describe how experiments are **designed using BMF models** to directly test the hypotheses proposed. Studies of GVHD in other hematological disorders will not be considered.*

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. BMFRP Strategic Plan

The BMFRP summarizes its programmatic interests and strategic direction in the BMFRP Strategic Plan. Applicants are strongly urged to review the near- and long-term goals in this document before preparing their applications. The BMFRP Strategic Plan is located at https://cdmrp.health.mil/bmfrp/pdfs/BMFRP%20Strategic%20Plan.pdf.

II.A.2. FY23 BMFRP Focus Areas

To meet the intent of the award mechanism, applications **must** address at least one of the FY23 BMFRP Focus Areas listed below. Selection of the appropriate Focus Area is the responsibility of the applicant.

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

II.A.3. Relevant BMF Diseases and Conditions

The BMFRP encourages research that improves the understanding and treatment of several BMF diseases and conditions. To assist the application review process, applicants **must** specify the disease or condition that will be 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's Disease
- SAMD9/SAMD9L Germline Mutations
- Severe Congenital Neutropenia
- Shwachman-Diamond Syndrome

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. 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.

II.A.4. Award History

The BMFRP Idea Development Award (IDA) mechanism was first offered in FY13. Since then, 293 IDA applications have been received, and 57 have been recommended for funding for a 19.5% fund rate.

II.B. Award Information

The BMFRP IDA is intended to support innovative ideas and high-impact approaches based on scientifically sound evidence to move toward the BMFRP's vision of understanding and curing BMF diseases. This award mechanism is designed to support new ideas. Proposed research studies should have a high probability of revealing new avenues of investigation. The research

project should include a well-formulated, testable hypothesis based on strong scientific rationale and a well-developed and articulated research approach. Personnel on the proposed team should have a strong background in BMF disease research.

This funding opportunity is open to Established Investigators (EIs) and Early-Career Investigators (ECIs). ECIs will be assessed using different criteria for personnel during the review process (refer to Section II.E.1.a, Peer Review).

The following are significant features of this award mechanism:

- **Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. This may include high-risk, potentially high-gain, approaches to BMF disease research, provided the application demonstrates the potential for significant impact on the field of research and/or patient care. Research that is only an incremental advance is *not* considered innovative.

- **Impact:** Proposed research projects should address a central critical issue or question in BMF disease research or clinical 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 translational potential of the project should be considered and described. Applications should address how the research will translate findings into prevention strategies and/or a cure for BMF diseases.

- **Rationale:** Preliminary data, such as unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on the application and/or data from the published literature relevant to BMF diseases and the proposed research project, may be included but are not required. If preliminary data are not included, the proposed research should be based on a strong rationale with sound logical support from published literature.

- **Personnel:** Personnel are considered a crucial element of the BMFRP IDA. The application should demonstrate expertise in BMF diseases through the PI's background or that of the research team or through collaboration. Collaborations should be documented.

    - **Established Investigator:** An EI applying for the IDA is defined as ***an independent investigator at or above the level of Associate Professor (or equivalent) or an Assistant Professor (or equivalent) with 10 years or more from their first faculty appointment (or equivalent).*** The EI should have BMF disease-related expertise and background as demonstrated by funding and publication records. The EI should plan research collaborations and dedicate a level of effort appropriate for the successful conduct of the proposed work.

    - **Early-Career Investigator:** An ECI applying for the IDA should be ***an independent investigator at the level of Assistant Professor (or equivalent) with less than 10 years from their first faculty appointment (or equivalent).*** Time spent on extended family medical leave will not count against the 10-year eligibility restriction, and associated

lapses in research time and appointments should be articulated in the application. Current appointment status and aggregate time from first faculty appointment (or equivalent) should be clearly articulated in the PI's biographical sketch. Postdoctoral fellows are not eligible as ECIs. The ECI's training should demonstrate the ECI's ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY23 BMFRP IDA should not exceed **$530,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $4.24M to fund approximately five IDA applications. Funding of applications received is contingent upon the availability of federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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. It is anticipated that awards made from this FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is

not required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trials are not allowed. The FY23 BMFRP is not offering an award mechanism that will support clinical trials; PIs requesting funding for a clinical trial are encouraged to investigate other funding agencies for support. ***A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual.
Note: Studies that meet the requirements for exemption under §46.104(d)(4) of the Common Rule are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

Research Involving Animals: All research funded by the FY23 BMFRP IDA involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO, Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal

Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD, and research institutes.

Intramural DOD Organization: A DOD laboratory, DOD military treatment facility, and/or DOD activity embedded within a civilian medical center. ***Intramural Submission:*** **An *application submitted by a DOD organization for an intramural investigator working within a DOD laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.***

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Established Investigators: Independent investigators at or above the level of Associate Professor (or equivalent) or Assistant Professors (or equivalent) with 10 years or more from their first faculty appointment (or equivalent) at the time of the application submission deadline are eligible to be named as the EI on the application. The EI should have BMF disease-related expertise and background as demonstrated by funding and publication records. The EI should plan research collaborations and dedicate a level of effort appropriate for the successful conduct of the proposed work.

Early-Career Investigators: Independent investigators at the level of Assistant Professor (or equivalent) who are less than 10 years from their first faculty appointment (or equivalent) at the time of the application submission deadline are eligible to be named as the ECI on the application. Time spent on extended family medical leave will not count against the 10-year eligibility restriction, and associated lapses in research time and appointments should be

articulated in the application. Current appointment status and aggregate time from first faculty appointment (or equivalent) should be clearly articulated in the PI's biographical sketch. ***Postdoctoral fellows are not eligible for ECI designation***. The ECI's training should demonstrate the ECI's ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

The CDMRP strongly encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at https://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or 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).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

The electronic Biomedical Research Application Portal (eBRAP) (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (https://grants.gov), receive

communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1, Full Application Guidelines).

The application title, eBRAP log number, 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. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an 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.

The applicant organization and associated PI identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

When starting the pre-application, PIs should ensure that they have selected the appropriate mechanism option in eBRAP:

- Idea Development Award - **Established Investigator** (**IDA-EI**)
- Idea Development Award - **Early Career Investigator** (**IDA-ECI**)

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Research & Related Form). The Business

Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY23 BMFRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  - **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:

    - **BMFRP Objective:** Describe how the proposed research adheres to the intent of the FY23 BMFRP program objective as described in Section II.A, Program Description. Identify the Relevant BMF Disease or Condition and FY23 BMFRP Focus Area(s) it seeks to address.

- **Research Idea:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research. Outline any preliminary data to be included, if applicable. State the hypothesis to be tested and/or the objective to be reached. State the project's specific aims. Clearly articulate how the research addresses a critical problem or question in BMF diseases.

- **Innovation:** Describe how the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other creative qualities.

- **Impact:** Explain the potential 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:** Clearly describe the BMF expertise of the PI and research team and how this will factor into their ability to successfully complete the proposed research. Articulate the eligibility of the PI as an EI or an ECI.

  - **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 (five-page limit per individual):** ***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.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the BMFRP, pre-applications will be screened based on the following criteria:

- **BMFRP Objective:** How well the proposed research adheres to the intent of the FY23 BMFRP objective. Whether the proposed research addresses at least one of the FY23 BMFRP Focus Areas.

- **Research Idea:** How well the rationale for the project is articulated through presentation of the ideas and reasoning behind the proposed research. Whether the preliminary data included support the research idea, if applicable. How well the hypothesis to be tested and/or objectives to be reached are stated. To what degree the proposed project addresses a critical problem or question in BMF diseases.

- **Innovation:** How well the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other creative qualities.

- **Impact:** To what degree the proposed research will make an important contribution that significantly advances current methods and concepts toward the BMFRP's vision of understanding and curing BMF diseases.

- **Personnel:**

  - Whether the PI meets the eligibility requirements as an EI or as an ECI.

  - To what degree the PI and research team's backgrounds and BMF disease-related expertise are appropriate to successfully carry out the proposed research project.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above

.II.D.2.b. Step 2: Full Application Submission Content

Applications will not be accepted unless notification of invitation has been received.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (https://grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for HT9425-23-BMFRP-IDA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for HT9425-23-BMFRP-IDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel

Extramural Submissions	Intramural DOD Submissions
• Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	• Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. ***Note:*** If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/ Comptroller/Task Area Manager or equivalent

Extramural Submissions	Intramural DOD Submissions
	Business Official should log into eBRAP to review and to approve prior to the application verification deadline.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

  SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative 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 (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an

unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the scientific rationale behind the proposed research and explain how this research demonstrates a critical understanding and in-depth analysis of BMF diseases. Describe previous experience most pertinent to the application. Preliminary data such as unpublished results from the laboratory of the PI or collaborators named on the application and/or data from the published literature relevant to the proposed research project may be included but are not required. If preliminary data are not included, the research should be based on sound rationale with logical support from published literature.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached. Identify the FY23 BMFRP Focus Area(s) the work seeks to address.

- **Specific Aims:** Concisely explain the project's specific aims. 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 in sufficient detail to evaluate its appropriateness and feasibility. Address potential problem areas and present alternative methods and approaches. If applicable, describe the statistical analysis plan with appropriate power analysis and explain how it supports the sample size. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), or international regulatory agency, if applicable. Research projects may include preclinical studies in animal models, or human subjects and human anatomical substances. If proposing studies utilizing previously acquired data or tissue specimens, provide proof of availability and access to the materials. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples, including patient availability, and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. 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/gender, 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, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. The inclusion strategy should agree with the enrollment table(s) provided in Attachment 2: Supporting Documents: Inclusion Enrollment Report.

Note: Innovation, Impact, and Translation Potential should not be addressed in the Project Narrative (Attachment 1) but instead should be articulated in Attachments 6, 7, and 8 respectively (see below).

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

  There are no page limits for any of these components unless otherwise noted. Include only those 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 (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

  - **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 and 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 should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no 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 a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

  - **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization demonstrating that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- **Intellectual Property:** Information can be found in the 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.

  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Inclusion Enrollment Report**: If proposing research involving human subjects, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c Enclosure 3, DoD Instructions 3200.12.

  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstracts are highly important:

- **Background:** Present the ideas and reasoning behind the proposed research.
- **Hypothesis/Objective:** State the hypothesis to be tested/objective to be reached. Identify the FY23 BMFRP Focus Area(s) the work seeks to address.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including the appropriate controls.
- **Innovation:** Briefly describe the novelty or paradigm shift proposed in the project and how it will yield critical discoveries, new avenues of investigation, or major advancements to prevent or cure BMF diseases.
- **Impact:** Summarize how the proposed project is relevant to and will have an impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be particularly impacted by the research.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community. ***Do not duplicate the technical abstract.***

  - State the FY23 BMFRP Focus Area(s) to be addressed by the proposed research.
  - Describe the objectives and rationale for the proposed research in a manner that will be ***readily understood by readers without a background in science or medicine***.
    - Describe the ultimate applicability of the research.
    - What bone marrow disease or condition is the study seeking to address and how will it help?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a person-related outcome?
  - Innovative aspects of the proposed research project.

- If the research is too basic 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/conditions?

- **Attachment 5: Statement of Work (four-page limit): Upload as "SOW.pdf".** The suggested Statement of Work (SOW) format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the IDA mechanism, refer to the "***Suggested SOW Strategy Generic Research***" document for guidance on preparing the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

- **Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf".**

  - Summarize how the proposed work is innovative.

  - Describe how the proposed research project introduces a new paradigm or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.

  - Describe how the research represents more than an incremental advance on published data or current work in the applicant's laboratory.

  - Explain how the potential level of gain for the research and/or patient community justifies the risk of the proposed research project.

- **Attachment 7: 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 why the proposed research project is important to understanding the causes and progression of BMF diseases and/or to realizing improvements in patient care.

  - 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.

- **Attachment 8: Translation Potential Statement (one-page limit): Upload as "Translation.pdf".**

  - Describe how the project is expected to translate promising research findings into prevention strategies and/or a cure for BMF diseases.

  - 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 these relationship(s) will be leveraged to ensure potential translation of study findings in the future.

- **Attachment 9: Early-Career Investigator Eligibility Statement, if applicable (one-page limit): Upload as "ECIeligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met. The letter should verify that the PI is at the level of Assistant Professor (or equivalent) and within 10 years from their first faculty appointment (or equivalent) at the time of the application submission deadline. Include the organizational commitment for independent laboratory space and protection of dedicated research time to conduct the proposed project. A suggested Early-Career Investigator Eligibility Statement template is available for download on the Full Announcement page in Grants.gov. For more eligibility details, refer to Section II.B, Award Information, and Section II.C, Eligibility Information.

- **Attachment 10: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 11: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in

science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf". The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  - **Intramural DOD Collaborator(s):** Complete the "Suggested Collaborating DOD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. ***As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.*** Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly

recommended, but not required. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.

Intramural DOD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$530,000.** If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the government exceeding **$530,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.

- Costs for two investigators to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the BMFRP IDA.

Must not be requested for:

- Clinical trial costs

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.***

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**
    - To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, published data, BMF disease-relevant preliminary data (if applicable), and/or logical reasoning.
    - To what degree the proposed research demonstrates a critical understanding and in-depth knowledge of BMF diseases.
    - How well the hypotheses or objectives, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
    - How well the work addresses one or both of the FY23 BMFRP Focus Area(s).

- To what degree the research design and methods can successfully achieve the goals of the proposed project.

- To what extent the application identifies potential problems and pitfalls, and addresses alternative approaches.

- Whether the application includes an appropriate statistical analysis plan with power analysis, if applicable. How well the described statistical analysis plan will evaluate the results, and if it is appropriate for the sample size according to the power analysis.

- Whether the application demonstrates the availability of resources such as tissue, data, or human subjects, if applicable.

- 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/gender, racial, and ethnic group.

- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or an international regulatory agency.

- **Innovation**

  - How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.

  - If applicable, to what degree the potential level of gain for the research and/or patient community justifies the risk of the proposed research project.

  - To what extent the proposed research represents more than an incremental advance upon published data or current research being performed in the applicant's laboratory.

- **Impact**

  - How the research project will make an important contribution that significantly advances the understanding of the causes and/or the progression of BMF diseases and/or improves patient care.

  - 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.

- **Personnel**
    - How appropriate the levels of effort are for successful conduct of the proposed work.
    - To what degree the expertise and background of the research team are appropriate to accomplish the proposed study.
    - For EIs only:
        - To what degree the BMF disease-related expertise and background of the EI are appropriate to accomplish the proposed work.
    - For ECIs only:
        - Whether the PI's previous training supports the abilities of the ECI to accomplish the proposed work.
        - Whether the institution, through its Letter(s) of Organizational Support, has demonstrated commitment (i.e., independent laboratory space, funding, etc.) to establish a career for the ECI in BMF disease research.

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the application:

- **Translation Potential**
    - How well the project will translate promising research findings into prevention strategies and/or a cure for BMF diseases.
    - 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.
- **Budget**
    - Whether the **direct** costs exceed the allowable direct 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.

II.E.1.b. 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 the peer reviewers
- Relevance to the mission of the DHP and FY23 BMFRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact with respect to the BMFRP objective
  - Relative innovation with respect to the BMFRP objective
  - Translational potential

II.E.2. Application Review and Selection Process

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 made to the Commanding General, USAMRDC. ***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 II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the BMFRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and

evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. 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 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 Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

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.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY23 funds are anticipated to be made no later than September 30, 2024. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit or for-profit 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. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. 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.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D General Terms and Conditions and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

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

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement ***(only required for clinical research studies and clinical trials)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

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 FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with 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 (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the "Synopsis" page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY23 BMFRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY23 BMFRP Programmatic Panel members can be found at https://cdmrp.health.mil/bmfrp/panels/panels23***.
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- 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.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.
- The application does not address at least one of the FY23 BMFRP Focus Area(s).
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The invited application proposes a different research project than that described in the pre-application.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application proposes a study primarily focused on myeloproliferative neoplasms, leukemia, or other malignancies.
- The application proposes a study addressing GVHD in stem cell transplant patients of non-BMF hematologic disorders.

II.H.2.d. 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 USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance **(extramural submissions only)**	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Innovation Statement: Upload as Attachment 6 with file name "Innovation.pdf"	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"	
	Translation Potential Statement: Upload as Attachment 8 with file name "Translation.pdf"	
	Early-Career Investigator Eligibility Statement: Upload as Attachment 9 with file name "ECIeligibility.pdf" if applicable	
	Representations, if applicable (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field	
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	
Budget **(intramural submissions only)**	Suggested DOD Military Budget Format, including justification	
Project/Performance Site Location(s) Form	Complete form as instructed	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
BMF	Bone Marrow Failure
BMFRP	Bone Marrow Failure Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ECI	Early-Career Investigator
EI	Established Investigator
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GVHD	Graft versus Host Disease
IACUC	Institutional Animal Care and Use Committee
IDA	Idea Development Award
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
R&D	Research and Development
SAM	System for Award Management
SF	Standard Form
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier

URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code