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

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-BMFRP-IIRA

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. FY23 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 Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY08, resulting in a single award. It was reintroduced in FY21 with significantly different attributes, leading to a receipt of 17 IIRA applications, representing 21 potential awards. Two applications have been recommended for funding for a funding rate of 11.8%.

II.B. Award Information

The FY23 BMFRP IIRA will offer two funding levels with different intent:

Funding Level 1 (FL1): To support studies that further develop mature ideas, expand upon key discoveries, and have the potential to make significant advances in research and/or patient care in the FY23 BMFRP Focus Areas. IIRA applications may involve translational and clinical research including studies in animal models, research with human data and/or anatomical substances, and research with human subjects, as well as correlative studies associated with an existing clinical trial; ***however, FL1 awards may not be used to support a clinical trial.*** Multidisciplinary collaborations are encouraged.

Funding Level 2 (FL2): To support Investigational New Drug (IND) application-enabling efforts. The BMFRP recognizes the scientific and financial challenges associated with advancing promising, potentially life-changing, therapeutic agents from the laboratory to clinical evaluation. Data related to lead compound characterization; formulation and stability; absorption, distribution, metabolism and excretion; dose/response; and toxicology are required before clinical trials can commence. The proposed studies under the FL2 IND-enabling efforts are expected to be empirical in nature, product-driven, and focused on the accumulation of data for a lead therapeutic candidate that will be included in an IND application submission to the U.S. Food and Drug Administration (FDA). ***At least one and no more than three lead therapeutic candidates must be named at the time of application submission to meet the intent of the FL2 mechanism.*** Library screening or drug optimization studies do not meet the intent of FL2. The intent of FL2 awards is to perform the necessary evaluation of promising therapies that will lead to clinical trials; however, ***clinical trials themselves are not supported by this mechanism.*** FL2 applications must address the FY23 BMFRP Focus Area, "Find effective BMF treatments and cures."

The following are significant features of this award mechanism:

- **Impact:** Proposed research projects should address a central critical issue or question in BMF disease research or 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. The proposed study should support the reciprocal transfer of information between basic and clinical science, or vice-versa, to further develop mature ideas and expand upon key discoveries. Applications should address how the research will translate findings into prevention strategies and/or a cure for BMF diseases.

- **Preliminary Data:** Observations that drive a research idea may be derived from laboratory discovery, population-based studies, a clinician's first-hand knowledge of patients, or anecdotal data. Applications must include preliminary and/or published data that are relevant to the mission of the BMFRP and support the proposed research project. Any unpublished preliminary data provided should originate from the laboratory of the Principal Investigator (PI) or a member(s) of the research team.

- **Multidisciplinary Collaborations:** Applicants are encouraged, but not required, to form multidisciplinary teams of investigators who bring specific skills that contribute to the successful completion of the project. This can include both intellectual input and research resources (e.g., supplies, reagents, equipment, personnel, services, tissue samples, access to patients or populations).

- **Correlative Studies:** Applications to FL1 are encouraged to propose correlative studies of open/ongoing or completed clinical trials to better characterize treatment response and provide deeper insights that can be used to develop future clinical trial endpoints or support personalized medicine approaches.

Partnering PI Option: The IIRA encourages applications that include meaningful and productive collaborations between investigators and includes an option for more than one PI. Electing to submit to the Partnering PI Option does not influence the total direct cost limit as outlined in Section II.D.5, Funding Restrictions. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

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 IIRA FL1 Award should not exceed **$675,000**, and the anticipated direct cost budgeted for the entire period of performance for an FY23 BMFRP IIRA FL2 award will not exceed **$850,000**. 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 $2.44M to fund approximately two IIRA 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 will not be supported by either funding level of the FY23 BMFRP IIRA. 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.

Rigor of Experimental Design: All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis SC et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature*, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to describe how these standards will be addressed. Refer to the application submission instructions for more information. Applicants should consult the Animal Research: Reporting *In Vivo* Experiments (ARRIVE) guidelines 2.0 to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at https://arriveguidelines.org/arrive-guidelines.

Research Involving Animals: All research funded by the FY23 BMFRP IIRA 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

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

Investigators at or above the level of Assistant Professor (or equivalent) may be named by the applicant organization as the PI or Partnering PI on the application.

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.

The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account. After associating the pre-application to their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated to their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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 (Single PI) or Initiating PI (Partnering PI Option) 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(s) 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:

- Investigator-Initiated Research Award – **Funding Level 1 (FL1)**

- Investigator-Initiated Research Award – **Funding Level 1 – Partnering PI Option (FL1-PPIO)**
- Investigator-Initiated Research Award – **Funding Level 2 (FL2)**
- Investigator-Initiated Research Award – **Funding Level 2 – Partnering PI Option (FL2-PPIO)**

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the eBRAP 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.

Partnering PI Option: The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.

- **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 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.

    - **Background/Research Problem:** State the background and scientific rationale on which the proposed research project is based. Relevant literature citations and preliminary data must be included. Clearly articulate how the research addresses a critical problem or question in BMF diseases. If applying to FL2, identify the lead therapeutic candidate(s), provide evidence of efficacy in preclinical models, and describe how the drug is sufficiently mature to justify pre-IND application characterization.

    - **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the scientific approach. Include a description of controls, as appropriate.

    - **Impact:** Explain the potential near- and long-term impact of the proposed research project and how it will move the research field toward achieving the BMFRP's vision to understand and cure BMF diseases.

- **Personnel:** Concisely describe the BMF expertise of the PI(s) and research team and how this will factor into their ability to successfully complete the proposed research.

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (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 Area(s).

  - **Background/Research Problem:** How well the background, scientific rationale, preliminary data, and/or relevant literature citation demonstrate sufficient evidence to support the proposed research project. To what degree does the research address a critical problem or question in BMF disease. If applicable, whether the evidence provided shows preclinical efficacy of the lead therapeutic candidate(s) and sufficient maturity to justify pre-IND application characterization.

  - **Specific Aims and Study Design:** How well the specific aims are stated and addressed in the outlined research project. How well the scientific approach (including controls) supports the evaluation of the specific aims proposed.

- **Impact:** To what degree the proposed research will make important near- and long-term contributions that significantly advances the research field toward the BMFRP's vision of understanding and curing BMF diseases.

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

- **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

(Single PI Preproposal) Applications will not be accepted unless notification of invitation has been received.

(Multiple PI Preproposal) Applications will not be accepted unless notification of invitation has been received by the Initiating PI.

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-IIRA 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-IIRA 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 • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form	**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 • 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"	**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

Extramural Submissions	Intramural DOD Submissions
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.***	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(s)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 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.

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

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 (12-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 ideas and reasoning behind the proposed research project, and clearly demonstrate that there is sufficient scientific evidence to support the proposed stage of research, including preliminary, published, and/or unpublished data. Cite relevant literature. If applying to FL2, identify the lead therapeutic candidate(s) that are to be characterized in support of an IND application filing. ***At***

least one, and no more than three, lead therapeutic candidates must be named at the time of application submission.

- **Objective:** State the objectives of the study.
- **FY23 BMFRP Focus Area:** State the FY23 BMFRP Focus Area(s) to be addressed by the proposed research.
- **Specific Aims:** Concisely explain the project's specific aims. The aims should agree with the primary aims and associated tasks described in the SOW (Attachment 5). If this research project is part of a larger study, present only the tasks that this award would fund.
- **Research Strategy:**
  - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility.
  - Describe the statistical plan including power analysis, as appropriate, for the proposed research.
  - Address potential problem areas and pitfalls, and present alternative methods and approaches.
  - If proposing a correlative study, specify how the proposed project complements the existing research efforts and provides additional relevant insight beyond the initial clinical trial study design.
  - If applicable, briefly describe the relevance of the chosen animal model to the BMF disease under investigation; full details will be required in the Animal Research Plan (Attachment 10).
  - If human subjects, anatomical samples, or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data. 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.
  - Describe how data will be reported. If the research will support therapeutic development, describe how the data reporting and documentation are appropriate for a regulatory filing with the FDA, or international regulatory agency, if applicable.

- **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 project, including sufficient scientific evidence to support the proposed stage of research. If applying to FL2, identify the lead therapeutic candidate(s) that are to be studied in support of an IND application filing.
- **Objective:** State the overall objective(s) of the study.
- **FY23 BMFRP Focus Area:** State the FY23 BMFRP Focus Area(s) to be addressed by the proposed research.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including the appropriate controls.
- **Impact:** Summarize how the proposed project is relevant to and will have a near- and long-term impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be 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
- If applying to FL2, identify the lead therapeutic candidate(s) that are to be studied in support of an IND application filing.
- 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/syndrome 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?

– 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/syndromes?

○ **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** The suggested 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 IIRA 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.

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

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf"**. ***The impact statement should be written with a broad audience in mind, including readers without a background in science or medicine.***

– Describe how the proposed research project will impact our understanding of the addressed FY23 BMFRP Focus Area(s) and make important contributions towards the goals of advancing BMF research and/or 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 7: Translation Potential Statement, if applicable (one-page limit, FL1 applications only): 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.

- Explain how the proposed study will support the reciprocal transfer of information between basic and clinical science, or vice-versa.

- 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 8: Transition Plan, if applicable (three-page limit, FL2 applications only): Upload as "Transition.pdf".** Describe/discuss the methods and strategies proposed to move the product to the next phase of development or delivery to the military or civilian market after successful completion of the award. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. The Transition Plan attachment should include the components listed below.

  - Details of the strategy, schedule, and milestones to transition to the next level of development and/or commercialization (e.g., partners, internal/external funding opportunities to be pursued). Include a description of collaborations and other resources that will be used to provide continuity of development.

  - The planned indication for the product label, if appropriate, and an outline of the development plan required to support that indication. Describe in detail the FDA regulatory strategy, to include considerations for compliance with Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice guidelines, if appropriate.

  - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. A "knowledge product" is a non-materiel product that addresses an identified need, Topic Area, or capability gap, is based on current evidence and research, aims to transition into medical practice, training, tools, or to support materiel solutions (systems to develop, acquire, provide, and sustain medical solutions and capabilities), and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.

  - A schedule and milestones for transitioning the technology or knowledge product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or civilian market, incorporation into clinical practice, or approval by the FDA). Include identification of the FDA regulatory strategy (if appropriate).

- Ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- A risk analysis for cost, schedule, manufacturability, and sustainability.

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

- **Attachment 10: Animal Research Plan (if applicable; three-page limit): Upload as "AnimalResPlan.pdf"**. When the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the IACUC. The Animal Research Plan should address the following points for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology. Be specific as to why the animal model was chosen over other models and how it is optimal for addressing the study aims and is relevant to the human BMF disease under investigation.

  - Summarize the procedures to be conducted. Describe how the study will be controlled.

  - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 11: Lead Therapeutic Candidate(s) Statement, if applicable (six-page limit, FL2 applications only): Upload as "Lead.pdf".** Provide the background information supporting the validation and further characterization of a proposed lead

therapeutic candidate(s) as a viable therapeutic approach. Explain how the proposed study is empirical in nature and product-driven.

- Provide the chemical (or biological) identities of the lead molecule(s) or limited group of specific compounds. ***At least one, and no more than three, lead therapeutic candidates must be named at the time of application submission to meet the intent of the FL2 mechanism.***

- Provide proof of identity and purity of the lead(s) (For small molecules, typically >95% by nuclear magnetic resonance, liquid chromatography-mass spectrometry (LC-MS), melting point, etc., with no single impurity >0.5%. For biologics, often by high-performance liquid chromatography, LC-MS, immunochemistry, nucleotide or amino acid sequence analysis, etc.).

- If applicable, provide data on primary and secondary in vitro bioactivity studies used for optimization or structure-activity relationships.

- Describe the putative mechanism of action. Provide data to support target selectivity, engagement, and desirable activity at the intended target.

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

- **Attachment 12: 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 13: 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 (NIH) 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.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate

Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI(s) even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 13. (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.

  Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. ***Note:*** Applicants should complete a separate military 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]) (Attachment 13) to show all direct and indirect costs. 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.

Application Components for the Partnering PI

The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, must complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

  - **Attachment 12: 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 13: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

  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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

  - 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, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  - **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.)

  - **Intramural DOD Collaborator(s):** Complete a separate DOD military 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]), and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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(s) 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 FY23 BMFRP IIRA offers two Funding Levels (FLs) with Partnering PI Options. ***It is the responsibility of the applicant(s) to select the Funding Level that is most appropriate for the proposed project.***

FL1 (single PI):

The maximum period of performance is 3 years.

- The application's direct costs budgeted for the entire period of performance should not exceed **$675,000**. 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 **$675,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate

FL1 with Partnering PI Option:

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

- The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$675,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct cost approved by the Government will not exceed **$675,000** or use an indirect cost rate exceeding each organization's negotiated rate.

FL2 (single PI):

- The maximum period of performance is **2** years.

- The anticipated direct costs budgeted for the entire period of performance will not exceed **$850,000**. 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 **$850,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

FL2 with Partnering PI Option:

- The maximum period of performance is **2** years.

The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$850,000**. If indirect cost

rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct cost approved by the Government will not exceed **$850,000** or use an indirect cost rate exceeding each organization's negotiated rate.

For All Funding Levels:

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 **2** or **3** years.

Partnering PI: The applications' combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **the maximum allowable costs for the selected funding level**. A separate award will be made to each PI's organization. The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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 IIRA.
- Costs to support FDA Regulatory expert consultation (FL2 applications only)

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**
    - How clearly the ideas and reasoning behind the proposed research project demonstrate sufficient scientific evidence, including preliminary data, to support moving into the proposed stage of research.
    - If applicable, whether an appropriate lead therapeutic candidate(s) has been identified for further characterization.
    - How well-developed and feasible the proposed research aims, experimental design, methods, and analysis support the research objectives.
    - How well the work addresses one or both of the FY23 BMFRP Focus Area(s).
    - How well statistical analysis plans, including power analysis, as appropriate, have been described to obtain meaningful results from the proposed research.
    - How thoroughly the application acknowledges potential problems or pitfalls and addresses alternative approaches.
    - If applicable, how well the proposed correlative study complements an existing research effort and to what degree it will provide additional relevant insight beyond the initial clinical trial study design.
    - If applicable, how well-designed each animal study is to achieve the objectives, including the endpoints to be used, and how well the selected animal model reproduces human disease.
    - If applicable, how well-established the human subject recruitment, data, or sample acquisition plans are to achieve the study objectives.
    - If applicable, whether a strategy for the inclusion of women and minorities appropriate to the objectives of the study was included and to what degree the rationale supports the composition of the proposed study population in terms of sex/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.

- **Impact**
  - How the research project, will impact our understanding of the addressed FY23 BMFRP Focus Area(s) and, if successful, make important contributions towards the goals of advancing BMF research and/or 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.

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

- **Translation Potential (FL1 applications only)**
  - How well the project will translate promising research findings into prevention strategies and/or a cure for BMF diseases.
  - Whether the proposed study will support the reciprocal transfer of information between basic and clinical science, or vice-versa.
  - How well the next steps to be taken to translate study results following the completion of the proposed study are described.
  - To what degree collaborations with clinicians or physician-scientists will be leveraged to ensure potential translation of study findings in the future.

- **Transition Plan (FL2 applications only)**
  - Whether the schedule and milestones for bringing the product to the next level of development (next-phase clinical trials, transition to industry, delivery to the military or

civilian market, incorporation into clinical practice, or approval by the FDA) are achievable.

- Whether the funding strategy described to bring the product to the next level of development (e.g., specific potential industry partners, specific funding opportunities to be applied for) is reasonable and realistic.

- How the regulatory strategy and the development plan to support the planned product label, if applicable, are appropriate and well-described.

- Whether the risk analysis for cost, schedule, manufacturability, and sustainability is realistic and reasonable.

- How well the application identifies intellectual property ownership, describes an appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement.

- **Lead Therapeutic Candidate (FL2 applications only)**

  - How strongly the background supports the applicant's reasoning that the proposed therapeutic approach is viable for clinical application.

  - To what extent the study is empirical in nature and product-driven.

  - To what degree the data shows selectivity and engagement for an intended target and elicits a desired activity.

  - How well the preliminary data support validation of an identified bioactive compound or group of lead compounds with demonstrated efficacy in at least two BMF-relevant model system.

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

- **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
  - Translational potential (FL1 applications only)
  - Clinical potential of therapeutic candidate(s) (FL2 applications only)

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(s) 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, 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

Partnering PI Option: An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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, Partnering PIs (if applicable), 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.
- **FL1 applications:** Translation Potential Statement is missing.
- **FL2 applications:** Transition Plan is missing.
- **FL2 applications:** Lead Therapeutic Candidate(s) Statement is missing.
- 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.
- 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.
- The application does not address at least one of the FY23 BMFRP Focus Area(s).
- Less than one or more than three lead therapeutic candidates are identified for characterization in support of an IND-enabling submission (FL2 applications only).
- 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.
- **Partnering-PI Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

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	Initiating PI Completed	Partnering PI 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"		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Translation Potential Statement (FL1 applications only): Upload as Attachment 7 with file name "Translation.pdf"		
	Transition Plan (FL2 applications only): Upload as Attachment 8 with file name "Transition.pdf" if applicable		
	Research Team Statement: Upload as Attachment 9 with file name "Team.pdf"		
	Animal Research Plan (if applicable): Upload as Attachment 10 with file name "AnimalResPlan.pdf"		
	Lead Therapeutic Candidate(s) Statement (FL2 applications only): Upload as Attachment 11 with file name "Lead.pdf" if applicable		
	Representations, if applicable (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf"		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
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)**	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
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
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FL1	Funding Level 1
FL2	Funding Level 2
FY	Fiscal Year
GVHD	Graft Versus Host Disease
IACUC	Institutional Animal Care and Use Committee
IIRA	Investigator-Initiated Research Award
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
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
PPIO	Partnering PI Option
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