I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524BMFRPIDA

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), July 17, 2024
- **Invitation to Submit an Application:** August 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 9, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 14, 2024
- **Peer Review:** December 2024
- **Programmatic Review:** January 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Bone Marrow Failure Research Program (BMFRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the BMFRP in FY08 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the BMFRP from FY08 through FY23 totaled $64.05 million (M). The FY24 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, prevention, and treatment of inherited and acquired BMF diseases to improve the health of affected Service Members and their Families, Veterans, and the general public.

II.A.1. FY24 BMFRP Focus Areas

To meet the intent of the funding opportunity, applications **must** address at least one of the FY24 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.2. Relevant BMF Diseases and Conditions

The objective of the 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 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
- VEXAS 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.3. Award History

The BMFRP Idea Development Award mechanism was first offered in FY13. Since then, 323 Idea Development Award applications have been received, and 62 have been recommended for funding.

II.B. Award Information

The BMFRP Idea Development Award (IDA) is intended to support innovative ideas and high-impact approaches based on scientifically sound evidence to move toward the BMFRP's vision of understanding and curing BMF diseases. This award mechanism is designed to support new ideas. Proposed research studies should have a high probability of revealing new avenues of investigation. The research project should include a well-formulated, testable hypothesis based on strong scientific rationale and a well-developed and articulated research approach. ***Hypothesis-driven correlative studies associated with clinical trials that meet the innovative intent of this award mechanism are encouraged.*** An application that proposes a correlative study should be associated with a clinical trial(s), and the proposed study should facilitate the generation of new hypotheses or advance the understanding of disease biology, treatment mechanisms, or other innovative and impactful outcomes. Funding to conduct the clinical trial itself is outside the scope of this funding opportunity.

This funding opportunity is open to Established Investigators (EIs) and Early-Career Investigators (ECIs). ECIs will be assessed using different criteria for personnel during the review process (refer to Section II.E.1.a, Peer Review). Independent of career level, personnel on the proposed team should have a strong background in BMF disease research.

The following are significant features of this award mechanism:

- **Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, reveal new avenues of investigation, or exhibit other creative qualities. This may include high-risk, potentially high-gain, approaches to BMF disease research. Research that is only an incremental advance is *not* considered innovative.

- **Impact:** Proposed research projects should address a central critical issue or question in BMF disease research and/or patient care. High-impact research, if successful, will significantly advance current methods and concepts for the prevention, detection, diagnosis, and/or treatment of BMF diseases.

- **Translational Potential:** The potential for translational potential of the project should be considered even if translation is considered a long-term goal and anticipated to occur well beyond the end of the proposed project. Applications should describe how the research will translate findings into an understanding of causes or progression of BMF diseases, or strategies for prevention or a cure.

- **Personnel:** The application should demonstrate expertise in BMF diseases through the Principal Investigator's (PI's) background or that of the research team or through collaboration. Collaborations should be documented.

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

    - **Early-Career Investigator:** An ECI applying for the IDA should be ***an independent investigator at the level of Assistant Professor (or equivalent) less than 10 years from obtaining their first faculty appointment (or equivalent).*** Time spent on extended family medical leave will not count against the 10-year eligibility restriction, and associated lapses in research time and appointments should be articulated in the application. Current appointment status and aggregate time from first faculty appointment (or equivalent) should be clearly articulated in the PI's biographical sketch. Postdoctoral or Clinical fellows are not eligible as ECIs. The ECI's training should demonstrate the ECI's ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, and dedicated research time should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

Advancing Women's Health Research and Innovation: CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from

men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

Nuclear Medicine: Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

For research involving animals, human subjects, human anatomical substances, or human cadavers, please see General Application Instructions, Appendix 6, for more information.

Clinical trials are not allowed.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 BMFRP Idea Development Award should not exceed **$530,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $4.24M to fund approximately five Idea Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

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

Early-Career Investigators: Independent investigators at the level of Assistant Professor (or equivalent) who are less than 10 years from obtaining their first faculty appointment (or

equivalent) at the time of the application submission deadline are eligible to be named as the ECI on the application. Time spent on extended family medical leave will not count against the 10-year eligibility restriction, and associated lapses in research time and appointments should be articulated in the application. Current appointment status and aggregate time from first faculty appointment (or equivalent) should be clearly articulated in the PI's biographical sketch. ***Postdoctoral or Clinical fellows are not eligible for ECI designation***. The ECI's training should demonstrate the ECI's ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

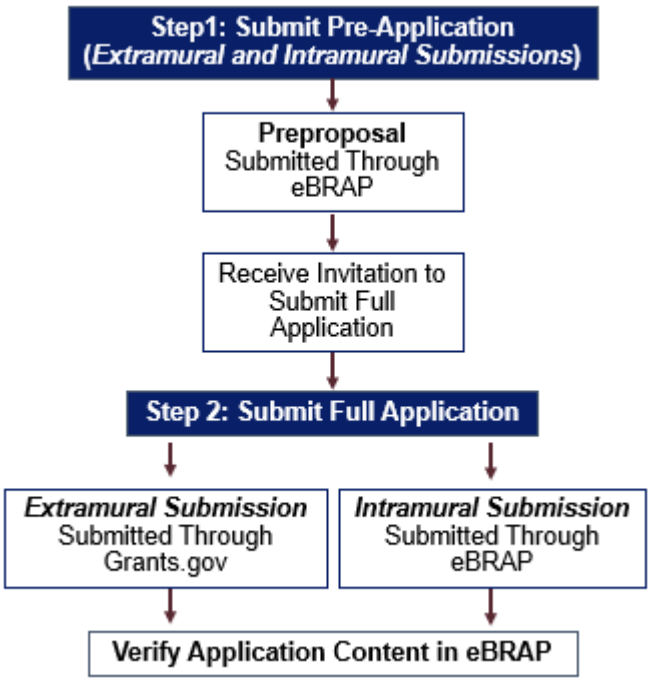
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524BMFRPIDA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524BMFRPIDA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

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

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 BMFRP Programmatic Panel members should not be involved in any pre-application or full 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.

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

All pre-application components must be submitted by the Initiating PI through eBRAP (https://eBRAP.org/).

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

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

Note: Upload documents as individual PDF files unless otherwise noted.

- **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 (uniform resource locators) 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 FY24 BMFRP program objective as described in Section II.A, Program Description. Identify the Relevant BMF Disease or Condition and FY24 BMFRP Focus Area(s) it seeks to address.

  - **Research Idea:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research. Outline any preliminary data to be included, if applicable. State the hypothesis to be tested and/or the objective to be reached. State the project's specific aims. Clearly articulate how the research addresses a critical problem or question in BMF diseases. If proposing a correlative study associated with a clinical trial(s), explain how the correlative study facilitates the generation of new hypotheses or advances the understanding of disease biology, treatment mechanisms, or other innovative and impactful outcomes to leverage and extend the impact of the clinical trial itself.

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

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

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

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

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

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

- **Key Personnel Biographical Sketches (five-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

II.D.2.a.ii. 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 FY24 BMFRP objective. Whether the proposed research addresses at least one of the FY24 BMFRP Focus Areas.

- **Research Idea:** How well the rationale for the project is articulated through presentation of the ideas and reasoning behind the proposed research. Whether the preliminary data included support the research idea, if applicable. How well the hypothesis to be tested and/or objectives to be reached are stated. To what degree the proposed project addresses a critical problem or question in BMF diseases. If a correlative study, how well it facilitates the generation of new hypotheses or advances the understanding of disease biology, treatment mechanisms, or other innovative and impactful outcomes to leverage and extend the impact of the clinical trial.

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

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

- **Personnel:**

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

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

II.D.2.a.iii. Notification of Pre-Application Screening Results

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

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

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (10-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

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

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached. Identify the FY24 BMFRP Focus Area(s) the work seeks to address.

- **Specific Aims:** Concisely explain the project's specific aims. If this research project is part of a larger study, present only the tasks that this award would fund.

- **Research Strategy:**

  - Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation of appropriateness and feasibility.

  - Address potential problem areas and pitfalls, and present alternative methods and approaches.

  - Describe how data will be reported and how it will be assured that the documentation will support an eventual regulatory filing with the U.S. Food and Drug Administration (FDA), or international regulatory agency, if applicable.

  - Research projects may include preclinical studies in animal models, or human subjects and human anatomical substances. If human data sets, human anatomical substances (blood, tumor tissue, etc.), and/or human participants will be used, provide evidence supporting the availability of and access to the proposed specimens/populations required for the study. Include a detailed plan for the acquisition of samples or the recruitment of participants, and for acquiring any additional research resources necessary for conducting the proposed research project. For projects that propose using human data sets and/or specimens from biobank(s), biorepository(s), and/or associated clinical trial(s), ***and if the manager or lead investigator is not the named PI or key personnel on the application, applicants should provide letter(s) of collaboration (see Attachment 2) from the manager or lead investigator for the source that details the applicant's access to the data sets/specimens and confirms the manager/lead investigator's commitment to provide the data sets/specimens.***

  - 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. The inclusion strategy

should agree with the enrollment table(s) provided in Attachment 2: Supporting Documents: Inclusion Enrollment Plan. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

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

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

  - Describe the clinical trial(s) the proposed study will correlate to and provide the clinicaltrials.gov ID number, if available.

  - Describe how the study will facilitate the generation of new hypotheses or advance the understanding of disease biology, treatment effects, or other innovative and impactful outcomes.

  - If the lead investigator of the clinical trial(s) is not the named PI or key personnel on this application, provide evidence of collaboration with the lead investigator of the clinical trial(s) and demonstrate access to the relevant patients, patient biological samples, patient data, or other patient resources necessary to conduct the proposed correlative study.

  - Describe the outcome measures to be captured and plans for data analysis.

Note: Innovation, Impact, and Translation Potential should be articulated in Attachments 6, 7, and 8 respectively (see below).

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.

  - **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 and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Letters of Access *(if applicable)*:** If access to patients, patient samples, patient datasets, or other resources is necessary to conduct the study, and the PI or key personnel on this application does not own the resource, provide a letter of support signed by the appropriate authorizing individual confirming access to the resource.

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

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

3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

  Use of DOD Resources *(if applicable)*: Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

  Use of U.S. Department of Veterans Affairs (VA) Resources *(if applicable)*: Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **Inclusion Enrollment Plan (*only required if clinical research is proposed*):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be 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 Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **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.*** 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. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the scientific rationale behind the proposed research project. If proposing a correlative study to an existing clinical trial(s), provide the clinicaltrials.gov ID number, if available.

  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Identify the FY24 BMFRP Focus Area(s) the work seeks to address.

  - **Specific Aims:** State the specific aims of the study.

  - **Study Design:** Describe the study design, including appropriate controls.

  - **Innovation:** Briefly describe the novelty or paradigm shift proposed in the project and how it will yield critical discoveries, new avenues of investigation, or major advancements to cure BMF diseases.

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

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations.

  - State the FY24 BMFRP Focus Area(s) to be addressed by the proposed research.

  - Describe the objectives and rationale for the proposed research in a manner that will be ***readily understood by readers without a background in science or medicine***.

    - Describe the ultimate applicability of the research.

    - What bone marrow disease or condition is the study seeking to address and how will it help?

    - What are the potential clinical applications, benefits, and risks?

    - What is the projected time it may take to achieve a person-related outcome?

- Describe the innovative aspects of the proposed research project.
- If the research is too basic for immediate clinical applicability, then describe the interim outcomes.
- What are the likely contributions of the proposed research project to advancing the field of BMF research and/or patient care among those with BMF diseases/conditions?
    - What is the projected time it may take to achieve a person-related outcome?

- **Attachment 5: Statement of Work (four-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  For the Idea Development Award, refer to the "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf".**
    - Summarize how the proposed work is innovative.
    - Describe how the proposed research project introduces a new paradigm or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.
    - Describe how the research represents more than an incremental advance on published data or current work in the applicant's laboratory.
    - Explain how the potential level of gain for the research and/or patient community justifies the risk of the proposed research project.
    - If a correlative study, explain how it will facilitate the generation of new hypotheses or advance the understanding of disease biology, treatment mechanisms, or other innovative outcomes.

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf".** ***The impact statement should be written with a broad audience in mind, including readers without a background in science or medicine.***
    - Describe how the proposed research project addresses the FY24 BMFRP Focus Area(s) and is important to understanding the causes and progression of BMF diseases, realizing improvements in patient care, and/or finding a cure.

- Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will directly result from the proposed research and explain how the outcomes will drive the BMF field forward and support new avenues for research or clinical care.

- Describe the long-term impact: Explain the potential long-term impact of this study on the field of BMF disease research and/or patient care.

- **Attachment 8: Translation Potential Statement (one-page limit): Upload as "Translation.pdf".** The potential for translation of the project should be considered even if translation is considered a long-term goal and anticipated to occur well beyond the end of the proposed project.

  - Describe how the project is expected to translate promising research findings into an understanding of causes or progression of BMF diseases, or strategies for prevention and/or a cure, and provide an anticipated timeline.

  - Include a description of the next steps in the translation of the results of this research after the end of the project.

  - Include a brief description of any collaborations with clinicians or physician-scientists for the proposed study. Describe how these relationship(s) will be leveraged to ensure potential translation of study findings in the future.

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

- **Attachment 10: Representations *(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 8, Section B, Representations.

- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire

period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

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

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

- **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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

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

The application's direct costs budgeted for the entire period of performance should not exceed **$530,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

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

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

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

Must not be requested for:

- Clinical trial costs

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Research Strategy and Feasibility**
    - To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, published data, BMF disease-relevant preliminary data (if applicable), and/or logical reasoning.
    - To what degree the proposed research demonstrates a critical understanding and in-depth knowledge of BMF diseases.

- How well the hypotheses or objectives, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
- To what degree the research design and methods can successfully achieve the goals of the proposed project.
- To what extent the application identifies potential problems and pitfalls and addresses alternative approaches.
- Whether the application demonstrates the availability of resources such as tissue, data, or human subjects, if applicable.
- If applicable, whether a strategy for the inclusion of women and minorities appropriate to the objectives of the study was included and to what degree the rationale supports the composition of the proposed study population in terms of sex/gender, racial, and ethnic group.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or an international regulatory agency.

- **Statistical Plan**
  - To what degree the statistical plan is appropriate for the proposed project, including any plans for blinding and randomization, as applicable.
  - How well the proposed sample size and the method by which it was derived, including power analysis calculation, are appropriate, as applicable.

- **Correlative Study (if applicable)**
  - Whether the associated clinical trial(s) is described in sufficient detail to assess the relevance and appropriateness of the proposed correlative study.
  - Whether the proposed correlative study will facilitate the generation of new hypotheses or advance understanding of disease biology, treatment effects, or other innovative and impactful outcomes.
  - Whether there is sufficient evidence of collaboration with the lead investigator of the associated clinical trial(s), or that the PI or key investigator of this application is also the lead investigator of the associated clinical trial(s).
  - Whether access to the relevant patients, patient biological samples, patient data, or other patient resources necessary to conduct the proposed correlative study is demonstrated.
  - Whether outcome measures and data analyses for the proposed correlative study are sufficiently described and appropriate for the study.

- **Innovation**
    - How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.
    - If applicable, to what degree the potential level of gain for the research and/or patient community justifies the risk of the proposed research project.
    - To what extent the proposed research represents more than an incremental advance upon published data or current research being performed in the applicant's laboratory.
- **Impact**
    - How well the proposed research project addresses one or both of the FY24 BMFRP Focus Area(s).
    - How the research project will make an important contribution to understanding of the causes and/or the progression of BMF diseases, realizing improvements in patient care, and/or finding a cure.
    - To what degree the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) will drive the BMF field forward and support new avenues for research or clinical care.
    - How well the anticipated long-term gains from this research will yield relevant results for BMF disease research or patient care.
- **Personnel**
    - How appropriate the levels of effort are for successful conduct of the proposed work.
    - To what degree the expertise and background of the research team are appropriate to accomplish the proposed study.
    - For EIs only:
        - To what degree the BMF disease-related expertise and background of the EI are appropriate to accomplish the proposed work.
    - For ECIs only:
        - Whether the PI's previous training supports the abilities of the ECI to accomplish the proposed work.
        - Whether the institution, through its Letter(s) of Organizational Support, has demonstrated commitment (i.e., independent laboratory space, funding, etc.) to establish a career for the ECI in BMF disease research.

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

- **Translation Potential**
    - How well the next steps to be taken to translate study results following the completion of the proposed study are described.
    - To what degree collaborations with clinicians or physician-scientists will be leveraged to ensure potential translation of study findings in the future.
- **Budget**
    - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
    - Whether the budget is appropriate for the proposed research.
- **Environment**
    - Whether the scientific environment is appropriate for the proposed research.
    - Whether the research requirements are supported by the availability of, and accessibility to, facilities and resources (including collaborative arrangements).
    - Whether the quality and extent of institutional support are appropriate for the proposed research.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 BMFRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition

- Relative impact with respect to the BMFRP objective
- Relative innovation with respect to the BMFRP objective
- Translational potential

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the BMFRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, 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 7, Section F, for general information on organization or PI changes.

II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

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

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

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 SAM 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 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

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 full application:

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

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the 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 FY24 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, including letters of support/recommendation. ***A list of the FY24 BMFRP Programmatic Panel members can be found at https://cdmrp.health.mil/bmfrp/panels/panels24***.
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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).
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The application does not address at least one of the FY24 BMFRP Focus Areas.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application proposes a different research project than that described in the pre-application.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application proposes a study primarily focused on myeloproliferative neoplasms, leukemia, or other malignancies.
- The application proposes a study addressing GVHD in stem cell transplant patients of non-BMF hematologic disorders.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1**,** upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3**,** upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4**,** upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5**,** upload as "SOW.pdf"	☐
Innovation Statement – Attachment 6, upload as "Innovation.pdf"	☐
Impact Statement – Attachment 7, upload as "Impact.pdf"	☐
Translational Potential Statement – Attachment 8, upload as "Translation.pdf"	☐
Early-Career Investigator Eligibility Statement (if applicable) – Attachment 9, upload as "ECIeligibility.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 10**,** upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 11, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐
Additional Application Components	☐
Confidential Letters of Recommendation	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
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
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FY	Fiscal Year
GVHD	Graft Versus Host Disease
IDA	Idea Development Award
IDA-ECI	Idea Development Award – Early Career Investigator
IDA-EI	Idea Development Award – Established Investigator
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
SAM	System for Award Management
SOW	Statement of Work
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
VA	U.S. Department of Veterans Affairs