

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: HT942524BMFRPIIRA

**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 FY24 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 Investigator-Initiated Research Award mechanism was first offered in FY21. Since then, 28 Investigator-Initiated Research Award applications have been received, and 4 have been recommended for funding.

II.B. Award Information

The FY24 BMFRP Investigator-Initiated Research Award (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 FY24 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 a clinical trial(s); *however, FL1 awards may not be used to support a clinical trial.* An application that proposes a correlative study should be associated with a clinical trial(s), and the proposed study should address critical knowledge gaps in clinical outcomes, validate key research results, expand upon potentially game-changing results, or other impactful outcomes. 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 FY24 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 an understanding of causes or progression of BMF diseases, or strategies for prevention and/or a cure.
- **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 clinical trials to better characterize treatment response, validate key research results, expand upon potentially game-changing results, or provide insights into disease biology, treatment mechanisms, or other disease-related complications.

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](#).

Rigor of Experimental Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in SC Landis 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 are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit [Attachment 8, Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>.

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 to the [General Application Instructions, Appendix 6](#), for more information.

Clinical Trials are not allowed under either funding level of the FY24 BMFRP IIRA.

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 Investigator-Initiated Research Award should not exceed **\$675,000 for Funding Level 1, or \$850,000 for Funding Level 2**. 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 \$2.44M to fund approximately two Investigator-Initiated Research 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

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. For titles outside of academia that may not be analogous to traditional hierarchies, investigators at or above an independent scientist level may be named by their organization as the PI or Partnering PI on the application.

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

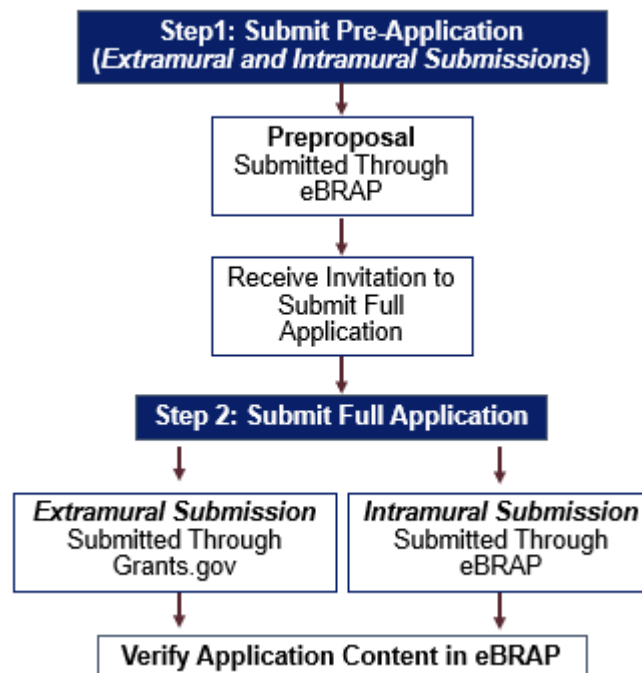
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission 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 HT942524BMFRPIIRA 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 HT942524BMFRPIIRA 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/>), including the submission of contact information for the Partnering PI [if exercising the Partnering PI Option].

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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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.

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**)

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

After associating the pre-application with their eBRAP account, the Partnering PI[(s)] should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with 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).

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

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

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.
- **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 anticipated scientific approach. Include a description of controls, as appropriate.

If proposing a correlative study associated with a clinical trial(s), (1) specify how the proposed project complements or extends the existing research efforts; and (2) explain how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-changing results, or provides insights into disease biology, treatment mechanisms, or other disease-related complications.
- **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 how the partners combined expertise and research team will better address the research question and lead to successful completion 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.

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:

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the 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 Area\(s\)](#).
- **Background/Research Problem:** How well the background, scientific rationale, preliminary data, and/or relevant literature citations demonstrate sufficient evidence to support the proposed research project. To what degree does the research address a critical problem or question in BMF disease. If applicable, 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 anticipated scientific approach (including controls) supports the evaluation of the specific aims proposed.

If a correlative study to an existing clinical trial(s), how well it complements or extends the existing research efforts and explains how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-changing results, or provides insights into disease biology, treatment mechanisms, or other disease-related complications.

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

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 for the PI or Initiating PI

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. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. *All associated applications (the Initiating PI's and each Partnering PI's) must be submitted by the full application submission deadline.*

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 (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 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 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.*** Details for each lead therapeutic candidate should be described in Attachment 11: Lead Therapeutic Candidate(s) Statement.

- **Objective:** State the objectives of the study. State the [FY24 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.
 - Address potential problem areas and pitfalls, and present alternative methods and approaches.

- If applicable, briefly describe the relevance of the chosen animal model to the BMF disease under investigation; full details will be required in the Animal Research Plan ([Attachment 10](#)).
- If human subjects, anatomical samples, or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data.
- 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.
- 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 (*required for FL2*).
- **Correlative Study (FL1 only, if applicable):**
 - Describe the clinical trial(s) the proposed study will correlate to and provide the clinicaltrials.gov ID number, if available.
 - Specify how the proposed correlative study complements or extends the existing efforts and explain how the study advances the characterization of treatment response, validates key research results, expands upon potentially game-changing results, or provides insights into disease biology, treatment mechanisms, or other disease-related complications.
 - If the lead investigator of the clinical trial(s) is not the named PI or key personnel on this application, provide evidence of collaboration with the lead investigator of the clinical trial(s) and demonstrate access to the relevant patients, patient biological samples, patient data, or other patient resources necessary to conduct the proposed correlative study.
 - Describe the outcome measures to be captured and plans for data analysis.
- **Statistical Plan:** Clearly describe the statistical plan and rationale for the statistical methodology and explain how it is appropriate for the proposed study. Provide a sample size estimate and the method by which it was derived, including power analysis calculation, as applicable. Include any plans for blinding and randomization.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** 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:** Only required for FL1 applications. Applications to FL2 will address the following items in [Attachment 8, Transition Plan](#). 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.
- **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 ideas and reasoning behind the proposed research project, including sufficient scientific evidence to support the proposed stage of research. If proposing a correlative study to a clinical trial(s), provide the clinicaltrials.gov ID number, if available. 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.
- **FY24 BMFRP Focus Area:** State the [FY24 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, 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 of scientific jargon, acronyms, and abbreviations.

- State the [FY24 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”.** 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 Investigator-Initiated Research 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.

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

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** *The impact statement should be written with a broad audience in mind, including readers without a background in science or medicine.*
 - Describe how the proposed research project addresses the [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 7: Translation Potential Statement, if applicable (one-page limit, required for FL1 applications only): Upload as “Translation.pdf”.**
 - Describe how the project is expected to translate promising research findings into advances in the understanding of BMF diseases or strategies for prevention and/or a cure.
 - 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, required for 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.

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

- **Attachment 10: Animal Research Plan (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 Institutional Animal Care and Use Committee (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, required for 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 (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 13: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](https://ebrap.org/eBRAP/public/Program.htm) 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. *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 even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*
- (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 13](#).

II.D.2.b.iii. Full Application Submission Components for the Partnering PI

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

- (a) SF424 Research & Related Application for Federal Assistance Form (*Extramural Submissions Only*):** Refer to the General Application Instructions, Section IV.B.(a), for detailed information.
- (b) Attachments:**
 - **Attachment 5: Statement of Work (five-page limit):** Upload as “SOW.pdf”. Each PI must submit an identical copy of a jointly created SOW.
 - **Attachment 12: Representations (*Extramural submissions only*):** Upload as “RequiredReps.pdf”.
 - **Attachment 13: Suggested Intragovernmental/Intramural Budget Form:** Upload as “IGBudget.pdf”.
- (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 information.
- (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 information.
 - **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.
 - **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 information.

- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.

The 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.

(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 General Application Instructions, Section V.A.(f), for detailed information.

(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 information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as [Attachment 13](#).

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 FY24 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. The government reserves the right to fund an application at a lower funding level.*

FL1 (single PI):

- The maximum period of performance is 3 years.
- The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI 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. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

FL1 with Partnering PI Option:

- The maximum period of performance is 3 years.
- The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI 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. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.
- 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.

FL2 (single PI):

- The maximum period of performance is **2** years.
- The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should 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.

FL2 with Partnering PI Option:

- The maximum period of performance is **2** years.
- The combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should 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.
- 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 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 **3** years (FL1) or **2** years (FL2).

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 for correlative studies associated with a clinical trial(s) (FL1 applications only), if applicable.
- Costs to support FDA Regulatory expert consultation (FL2 applications only)

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**
 - How clearly the ideas and reasoning behind the proposed research project demonstrate sufficient scientific evidence, including preliminary data, to support moving into the proposed stage of research.
 - How well-developed and feasible the proposed research aims, experimental design, methods, and analysis support the research objectives.
 - How thoroughly the application acknowledges potential problems or pitfalls and addresses alternative approaches.
 - 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.
- **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 (FL1, if applicable)**

- Whether the associated clinical trial(s) is described in sufficient detail to assess the relevance and appropriateness of the proposed correlative study.
- How well the proposed correlative study complements or extends the existing research efforts and provides additional relevant insight beyond the clinical trial(s) itself and will advance the characterization of treatment response, validate key research results, expand upon potentially game-changing results, or provides insights into disease biology, treatment mechanisms, or other disease-related complications.
- Whether there is sufficient evidence of collaboration with the lead investigator of the associated clinical trial(s), or that the PI or key investigator of this application is also the lead investigator of the associated clinical trial(s).
- Whether access to the relevant patients, patient biological samples, patient data, or other patient resources necessary to conduct the proposed correlative study is sufficiently demonstrated.
- How well the outcome measures and data analyses for the proposed correlative study are described and appropriate for the study.

- **Impact**

- How well the research project addresses [FY24 BMFRP Focus Area\(s\)](#) and, if successful, will make important contributions towards understanding the causes and progression of BMF diseases, realizing improvements in patient care, and/or finding a cure.
- To what degree the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) will drive the BMF field forward and support new avenues for research or clinical care.
- How well the anticipated long-term gains from this research will yield relevant results for BMF disease research or patient care.

- **Research Team**

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

For Partnering PI applications only:

- How the partners' combined expertise will better address the research question.
- How well the plans for collaboration and communication throughout the project are described and will be sufficient to facilitate a successful research project.
- **Translation Potential (Required for FL1 applications only)**
 - How well the project will translate promising research findings into advances in the understanding of BMF diseases or strategies for prevention and/or a cure.
 - Whether the proposed study will support the reciprocal transfer of information between basic and clinical science, 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 (Required for 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 (Required for FL2 applications only)**
 - Whether an appropriate lead therapeutic candidate(s), but no more than three, has been identified for further characterization.

- How strongly the background supports the applicant's reasoning that the proposed therapeutic approach is viable for clinical application.
- To what extent the study is empirical in nature and product-driven.
- To what degree the data shows selectivity and engagement for an intended target and elicits a desired activity.
- How well the preliminary data support validation of an identified bioactive compound or group of lead compounds with demonstrated efficacy in at least two BMF-relevant model systems.

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

- **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
 - 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>.

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

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

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

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 (previously Office of Research Protections), prior to implementation. This administrative review requirement is in addition to the local IACUC, 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-application 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.
- **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 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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- The invited application proposes a different research project than that described in the pre-application.
- The application does not address at least one of the [FY24 BMFRP Focus Area\(s\)](#).
- 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	
	PI/Initiating PI	Partnering PI
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”	☐	☐
Impact Statement – Attachment 6, upload as “Impact.pdf”	☐	☐
Translation Potential Statement (FL1 applications only) – Attachment 7, upload as “Translation.pdf”	☐	☐
Transition Plan – Attachment 8, upload as “Transition.pdf”	☐	☐
Research Team Statement – Attachment 9, upload as “Team.pdf”	☐	☐
Animal Research Plan (if applicable) – Attachment 10, upload as “AnimalResPlan.pdf”	☐	☐
Lead Therapeutic Candidate(s) Statement (FL2 applications only) – Attachment 11, upload as “Lead.pdf”	☐	☐
Representations (Extramural submissions only) – Attachment 12, upload as “RequiredReps.pdf”	☐	☐
Suggested Intragovernmental/Intramural Budget Form (if applicable) – Attachment 13, 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 (<i>Extramural submissions only</i>) Include budget justification	☐	☐
Budget (<i>Intramural submissions only</i>) Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (<i>if applicable</i>)	☐	☐
Additional Application Components	☐	☐
Confidential Letters of Recommendation	☐	☐

APPENDIX 1: ACRONYM LIST

ARRIVE	Animal Research: Reporting of 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
ET	Eastern Time
FAD	Funding Authorization Document
FDA	Food and Drug Administration
FL1	Investigator-Initiated Research Award – Funding Level 1
FL1-PPIO	Investigator-Initiated Research Award – Funding Level 1-Partnering PI Option
FL2	Investigator-Initiated Research Award – Funding Level 2
FL2-PPIO	Investigator-Initiated Research Award – Funding Level 2-Partnering PI Option
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
LC-MS	Liquid Chromatography-Mass Spectrometry
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PI	Principal Investigator
PPIO	Partnering PI Option
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