

# **Program Announcement**

**for the**

**Defense Health Program**

**Defense Medical Research and Development Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Bone Marrow Failure Research Program**

### **Idea Development Award**

**Funding Opportunity Number: W81XWH-15-BMFRP-IDA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), April 21, 2015
- **Invitation to Submit an Application:** June 3, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, July 21, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, July 24, 2015
- **Peer Review:** September 2015
- **Programmatic Review:** November 2015

*The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2015 (FY15) Bone Marrow Failure Research Program (BMFRP)) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The BMFRP was initiated in FY08 to promote innovative research focused on bone marrow failure (BMF) diseases. Appropriations for the BMFRP from FY08 through FY14 totaled \$23.35 million (M). The FY15 appropriation is \$3.2M.

The vision of the BMFRP is to understand and cure 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 of inherited and acquired BMF diseases to improve the health of individuals, with the ultimate goals of prevention and cure.

**FY15 BMFRP Objective:** To fund scientifically meritorious research focused on BMF diseases and their long-term sequelae. Investigator-initiated research is encouraged in the areas of congenital or acquired BMF. Studies focused on BMF diseases and their progression to other malignancies such as leukemia are acceptable. *However, research primarily focused on myeloproliferative neoplasms, leukemia, or other malignancies is discouraged.* Stem cell biology studies and translational projects including bone marrow transplantation studies should be clearly related to BMF diseases.

### B. Award Information

The BMFRP Idea Development Award is intended to support innovative ideas and high-impact approaches based on scientifically sound evidence to move toward the BMFRP vision of understanding and curing BMF diseases. This award mechanism is designed to support new ideas. Proposed research studies should have a high probability of revealing *new* avenues of investigation. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale and a developed and well-articulated research approach. Personnel on the proposed team should have a strong background in BMF research. ***This funding opportunity is open to established and early career investigators.***

***New for FY15: To encourage the application of early career investigators*** to the FY15 Idea Development Award Program Announcement/Funding Opportunity, the FY15 BMFRP has included an opportunity for one or more scientifically meritorious applications from applicants fitting the outlined description of an early career investigator. All early career investigators will be assessed using different criteria for Personnel during the review process ([Section III. B.1, Personnel](#)). The definition of an early career investigator for the BMFRP is an investigator within 10 years of completing a terminal degree (doctorate or any medical degree), excluding

time spent in medical residency, or during family medical leave. This should be clearly articulated by the applicant in the biographical sketch.

The following are significant features of this award mechanism:

1. **Research Approach:** The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of BMF. Experimental strategies may be novel or may be based on strong rationale derived from previously published data, presented preliminary data, or literature review. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. Additionally, resources should be identified and supported through documentation. Identification of potential problems and pitfalls are strongly encouraged with alternate approaches addressed. A statistical analysis of the proposed research should be included, if applicable, as well as a power analysis to support the design and sample size.
2. **Preliminary Data:** Preliminary data such as unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application and/or data from the published literature relevant to BMF and the proposed research project may be included but are not required. If preliminary data are not included, the proposed research should be based on a strong rationale with sound logical support from published literature.
3. **Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. This may include high-risk, potentially high-gain, approaches to BMF research, provided that there is the potential for significant impact on the field of research, and/or patient care and/or quality of life. Research that is merely an incremental advance is *not* considered innovative.
4. **Impact:** Proposed research projects should address a central critical issue or question in BMF research or clinical care. High-impact research will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, and/or treatment of BMF.
5. **Personnel:** Personnel are considered a crucial element of the BMFRP Idea Development Award. The application should demonstrate the investigator's expertise in BMF through the PI's background, research team, or through collaboration. Collaborations should be documented.
  - The established investigator (EI) should be at or above the level of Associate Professor (or equivalent). The established investigator should have BMF-related expertise and background as demonstrated by funding and publication records. The established investigator should plan research collaborations and dedicate a level of effort appropriate for the successful conduct of the proposed work.
  - The early career investigator (ECI) should be an independent investigator at the level of Assistant Professor, Instructor, or Assistant Research Professor (or

equivalent) and less than ten years from their terminal degree (excluding time spent in medical residency, or during family medical leave). The early career investigator's training (postdoctoral or clinical) should demonstrate that the ECI will be able to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

**Research Involving Human Anatomical Substances, Human Subjects, or Human**

**Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

***Clinical trials are not allowed.*** A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The FY15 BMFRP is not offering an award mechanism that will support clinical trials; PIs requesting funding for a clinical trial are encouraged to investigate other funding agencies for support. Additional information may be found at <https://ebrap.org/eBRAP/public/Program.htm> and in the General Application Instructions, Appendix 6.

***The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.***

**C. Eligibility Information**

- Investigators at or above the level of Associate Professor (or equivalent) are eligible to apply as EI. Investigators at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and less than ten years from their terminal degree (excluding time spent in medical residency, or during family medical leave) at the time

of application submission deadline are eligible to apply as ECIs. *Postdoctoral fellows are not eligible for the designation of ECIs.*

- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **D. Funding**

- The maximum period of performance is **2** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$360,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$360,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

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

- Salary
- Research supplies
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel costs to attend scientific/technical meetings

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. *In such cases, the extramural investigator must include a letter from the intramural collaborator's*

***Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

***The CDMRP expects to allot approximately \$2.88M of the \$3.2M FY15 appropriation to fund approximately five BMFRP Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## **II. SUBMISSION INFORMATION**

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the

full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-BMFRP-IDA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission and Content Form**

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY15 BMFRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
  - To avoid COIs during the screening and review process, list all individuals other than collaborators and key personnel who may have a COI in the review of the

application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

*Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

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

The Preproposal Narrative should include the following:

- **Intent of the Program Objectives:** Describe how the proposed research adheres to the intent of the program award description.
- **Research Idea:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research. Outline any preliminary data to be included, if applicable. State the hypothesis to be tested and/or the objective to be reached. Clearly articulate how the research addresses the goals of the BMFRP. State the project's specific aims.
- **Innovation:** Describe how the proposed research is innovative and how the research represents more than an incremental advance on published data.
- **Impact:** Explain the potential impact of the proposed research project and how it will, if successful, move the research field toward achieving the BMFRP's vision to understand and cure BMF diseases.
- **Personnel:** Clearly describe the BMF expertise of the research team and how this will factor into their ability to successfully complete the proposed research. Articulate the eligibility of the PI as an ECI or an EI.

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

- **References Cited (one-page limited):** 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, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (five-page limit per individual):** Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-Application – Tab 6**

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

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

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

- **Adherence to the intent of the award mechanism**
- **Research Idea:** How well the proposed project addresses a critical problem or question in BMF research. How well the proposed research focuses on FY15 BMFRP objectives. Whether any preliminary data included supports the research idea.
- **Innovation:** How well the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other creative qualities.
- **Impact:** To what degree the proposed research, if successful, will make an important contribution that significantly advances current methods and concepts toward the BMFRP vision of understanding and curing BMF diseases.
- **Personnel:**
  - Whether the PI meets the eligibility requirements as an ECI or as an EI.
  - To what degree the PI and research team’s backgrounds and BMF-related expertise are appropriate to successfully carry out the proposed research project.
- Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity.

### **C. Application Submission Content and Forms**

*Applications will not be accepted unless the PI has received notification of invitation.*

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

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

**Grants.gov application package components:** For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

**1. SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

**2. Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1:** Project Narrative (eight-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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below and also including the information required in section IB.

- **Background:** Present the ideas and reasoning behind the proposed research. Describe previous experience most pertinent to this application. Preliminary data such as unpublished results from the laboratory of the PI or collaborators named on this application and/or data from the published literature relevant to the proposed research project may be included but are not required. If preliminary data are not included, the research should be based on sound rationale with logical support from published literature.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Concisely explain the project’s specific aims. If this research project is part of a larger study, present only the tasks that the DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Include specific examples of key elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If applicable, describe the statistical plan with appropriate power analysis and how it supports the sample size. Research projects may include preclinical studies in animal models and human subjects and human anatomical substances. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. ***This award may not be used to conduct clinical trials. Note: Impact and innovation should not be addressed in the Project Narrative (Attachment 1), but instead should be articulated in Attachments 6 and 7, respectively (see below).***
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will be removed or may result in administrative withdrawal of the application.***
  - **References Cited:** List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not 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 Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copy/copies of the published manuscript(s) must 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/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. The technical abstract should address the following elements:

- Background: Present the ideas and reasoning behind the proposed research.
- Hypothesis/Objective: State the hypothesis/objective to be tested.

- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design, including the appropriate controls.
- Innovation: Briefly describe the novel or paradigm shift proposed in the project and how it will yield critical discoveries, new avenues of investigation, or major advancements to prevent or cure BMF diseases.
- Impact: Summarize how the proposed project is relevant to and will have an impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be particularly impacted by the research.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the lay abstract for appropriate description of the project’s key aspects. Do not duplicate the technical abstract. Include an overview of the proposed research project that can be readily understood by lay persons. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

- Background, hypothesis, or objectives
- The critical problem or question to be addressed by the proposed research project
- Identify the specific BMF disease to be researched or the overarching problem to be addressed
- Innovative aspects of the proposed research project
- The impact that the proposed research project results might have on the field of BMF research and/or patient care in the short and/or long term.
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Idea Development Award mechanism, use the SOW format example titled “**SOW (Statement of Work) Generic Format.**” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.
- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf”
  - Describe why the proposed research project is important to understanding the causes and progression of BMF and/or to realizing improvements in patient care and/or quality of life.

- Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will directly result from the proposed research.
- Describe the long-term impact: Explain the potential long-term impact of this study on the field of research and/or patient care.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf”

Summarize how the proposed work is innovative.

- Describe how the proposed research project introduces a new paradigm, challenges existing paradigms, or looks at existing problems or issues from a new perspective.
- Describe how the research represents more than an incremental advance on published data, or current work in the applicant’s laboratory.
- If the proposed research project is high-risk, explain the potential gain from accomplishing the work and finding the outcomes.
- **Attachment 8: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- 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 five-page National Institutes of Health Biographical Sketch may also be used.
- 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.”

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. 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/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **E. Submission Dates and Times**

All submission dates and times are indicated on the title page of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

#### **F. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and BMFRP, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review 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 process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

#### **B. Application Review Process**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
  - **Research Strategy and Feasibility**
    - To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, published data, BMF-relevant preliminary data (if applicable), and/or logical reasoning.
    - To what degree the proposed research demonstrates a critical understanding and in depth knowledge of BMF.
    - How well the hypotheses or objectives, specific aim, experimental design, methods, and analyses are developed and integrated into the project.
    - To what degree the research design and methods can successfully achieve the goals of the proposed project.
    - To what extent the PI identifies potential problems, pitfalls, and addresses alternative approaches.
    - Whether the application includes an appropriate statistical plan with power analysis, if applicable. How well the described statistical plan will evaluate the

results and if it is appropriate for the sample size according to the power analysis.

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

- **Innovation**

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- To what degree the potential level of gain for the research community or patient community justifies the risk of the proposed research project.
- To what extent the proposed research represents more than an incremental advance upon published data, or current research being performed in the applicant's laboratory.

- **Impact**

- How the research project, if successful, will make an important contribution that significantly advances our understanding of the causes and/or the progression of BMF and/or improves patient care and/or quality of life.
- 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 course will yield relevant results for BMF research or clinical care.

- **Personnel**

- For EIs:
  - Whether the applicant meets the PI eligibility requirements.
  - To what degree the BMF-related expertise and background represented on the research team is appropriate to accomplish the proposed work.
  - To what extent the levels of effort are appropriate for successful conduct of the proposed work.
- For ECIs only:
  - Whether the applicant meets the PI eligibility requirements as an ECI.
  - Whether training (postdoctoral or clinical) supports the abilities of the ECI to accomplish the proposed work.
  - Whether the ECI has demonstrated institutional commitment other than funding to establish a career in BMF.
  - To what extent the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Environment**

- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- How 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.
- Whether there is institutional commitment to the research and the applicant (applicable for ECIs only)

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

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

- a. Ratings and evaluations of the peer reviewers**

- b. Relevance to the mission of the DHP and FY15 BMFRP objective, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance to the FY15 BMFRP objective
- Relative impact and innovation

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **D. Application Review Dates**

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

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

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

The following will result in administrative rejection of the application:

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

### **B. Modification**

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

### **C. Withdrawal**

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

- A FY15 BMFRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY15 BMFRP IP members can be found at <http://cdmrp.army.mil/bmfrp/panels/panels15>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

#### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.

#### **D. Reporting**

Refer to the General Application Instructions, Appendix 3, Section J, for general information on reporting requirements.

## **E. Award Transfers**

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

Refer to the General Application Instructions, Appendix 3, Section N, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

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

Phone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf"	
	8	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 8 with file name "MFBudget.pdf", if applicable	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	