I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-BMFRP-IDA

Catalog of Federal Domestic Assistance 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 13, 2017
• Invitation to Submit an Application: August 22, 2017
• Application Submission Deadline: 11:59 p.m. ET, October 5, 2017
• End of Application Verification Period: 5:00 p.m. ET, October 10, 2017
• Peer Review: November 2017
• Programmatic Review: January 2018

This Program Announcement must be read in conjunction with the General Application Instructions version 20170418. The General Applications 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.”
# TABLE OF CONTENTS

I. OVERVIEW OF THE FUNDING OPPORTUNITY ................................................................. 1

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY .................. 3
   II.A. Program Description .................................................................................................. 3
   II.B. Award Information ..................................................................................................... 3
   II.C. Eligibility Information ............................................................................................... 6
      II.C.1. Eligible Applicants .......................................................................................... 6
      II.C.2. Cost Sharing ...................................................................................................... 7
      II.C.3. Other .................................................................................................................. 7
   II.D. Application and Submission Information ................................................................. 7
      II.D.1. Addresses to Request an Application Package .................................................. 8
      II.D.2. Content and Form of the Application Submission ............................................ 8
      II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM) ................................................................. 21
      II.D.4. Submission Dates and Times .......................................................................... 21
      II.D.5. Funding Restrictions ....................................................................................... 22
      II.D.6. Other Submission Requirements ..................................................................... 23
   II.E. Application Review Information ............................................................................. 23
      II.E.1. Criteria ............................................................................................................... 23
      II.E.2. Application Review and Selection Process ....................................................... 26
      II.E.3. Integrity and Performance Information ............................................................ 26
      II.E.4. Anticipated Announcement and Federal Award Dates ..................................... 27
   II.F. Federal Award Administration Information ............................................................ 27
      II.F.1. Federal Award Notices .................................................................................... 27
      II.F.2. Administrative and National Policy Requirements ........................................... 28
      II.F.3. Reporting ......................................................................................................... 28
   II.G. Federal Awarding Agency Contacts ...................................................................... 29
      II.G.1. CDMRP Help Desk ....................................................................................... 29
      II.G.2. Grants.gov Contact Center ............................................................................. 29
   II.H. Other Information ................................................................................................. 29
      II.H.1. Program Announcement and General Application Instructions Versions .... 29
      II.H.2. Administrative Actions .................................................................................. 30
      II.H.3. Application Submission Checklist .................................................................. 32

APPENDIX 1: ACRONYM LIST ............................................................................................. 33
II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Bone Marrow Failure Research Program (BMFRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The BMFRP was initiated in FY08 to provide support for research of exceptional scientific merit and promote innovative research focused on bone marrow failure (BMF) diseases. Appropriations for the BMFRP from FY08 through FY16 totaled $29.55 million (M). The FY17 appropriation is $3M.

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.

FY17 BMFRP Objective: To fund scientifically meritorious research focused on BMF diseases. 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.

II.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. The research project should include a well-formulated, testable hypothesis based on strong scientific rationale and a well-developed and articulated research approach. Personnel on the proposed team should have a strong background in BMF research. The anticipated direct costs budgeted for the entire period of performance for an FY17 BMFRP Idea Development Award will not exceed $315,000. Refer to Section II.D.5., Funding Restrictions, for detailed funding information.

This funding opportunity is open to established investigators (EIs) and early career investigators (ECIs). The FY17 BMFRP has included an opportunity for one or more
scientifically meritorious applications from applicants fitting the outlined description of an early career investigator. Early career investigators will be assessed using different criteria for personnel during the review process (refer to Section II.E.1.a., Peer Review). The BMFRP defines the early career investigator as being within 10 years of completing a terminal degree (doctorate or any medical degree), excluding time spent in medical residency, or during family medical leave. The applicant should clearly delineate how he/she meets these eligibility criteria in the biographical sketch. **Time spent as a postdoctoral fellow is not excluded and must be within the 10-year span from the time of terminal degree.** Postdoctoral fellows are not eligible to apply as early career investigators.

The following are significant features of this award mechanism:

- **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 is 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.

- **Preliminary Data:** Preliminary data, such as unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on the application and/or data from the published literature relevant to BMF 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.

- **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 the application demonstrates the potential for significant impact on the field of research and/or patient care and/or quality of life. Research that is only an incremental advance is not considered innovative.

- **Impact:** Proposed research projects should address a central critical issue or question in BMF 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 diseases.

- **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, the research team, or through collaboration. Collaborations should be documented.
An established investigator (EI) applying for the Idea Development Award is an independent investigator at or above the level of Assistant Professor (or equivalent) and 10 years or more from a terminal degree. The established investigator should have BMF-related expertise and background as demonstrated by funding and publication records. The EI should plan research collaborations and dedicate a level of effort appropriate for the successful conduct of the proposed work.

An early career investigator (ECI) applying for the Idea Development Award should be an independent investigator at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and less than 10 years from their terminal degree (excluding time spent in medical residency or during family medical leave). This should be clearly articulated by the applicant in the biographical sketch. Postdoctoral fellows are not eligible to apply as ECIs. The early career investigator’s training (postdoctoral or clinical) should demonstrate the ECI’s ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project.

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) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of 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/EC. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (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 (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The FY17 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.
**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” *Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions, Appendix 1, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement 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 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1., Federal Award Notices.

**II.C. Eligibility Information**

**II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including international organizations, are eligible to apply.

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

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

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission:* Application submitted by a non-DoD organization to Grants.gov.

**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission:* Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.
**Note:** Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

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

**II.C.1.b. Principal Investigator:** Includes individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

**Established Investigators:** Independent investigators at or above the level of Assistant Professor (or equivalent) and 10 years or more from a terminal degree are eligible to apply as EIs.

**Early Career Investigators:** Independent investigators at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and less than 10 years from their terminal degree (excluding time spent in medical residency or during family medical leave) at the time of the application submission deadline are eligible to apply as ECIs. *Time spent as a postdoctoral fellow is not excluded and must be within the 10-year span from the time of terminal degree. Postdoctoral fellows are not eligible for ECI designation.*

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

**II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

**II.C.3. Other**

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

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

Refer to [Section II.H.2., Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

**II.D. Application and Submission Information**

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

*Extramural Submission* is defined as an application submitted by a non-DoD organization to Grants.gov.
**Intramural Submission** is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

### II.D.1. Addresses to Request an Application Package

**Submitting Extramural and Intramural Organizations:** Pre-application content and forms can be accessed at the electronic Biomedical Research Application Portal (eBRAP) [https://eBRAP.org](https://eBRAP.org).

**Submitting Extramural Organizations:** Full application packages can be accessed at [Grants.gov](https://www.grants.gov).

**Submitting Intramural DoD Organizations:** Full application packages can be accessed at [eBRAP.org](https://eBRAP.org).

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

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

Submission is a two-step process requiring both **pre-application** and **full application** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

**Pre-Application Submission:** All pre-applications from both extramural and intramural organizations must be submitted through the electronic Biomedical Research Application Portal (eBRAP) ([https://eBRAP.org](https://eBRAP.org)).

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.

**Full Application Submission:** Full applications must be submitted though the online portals as described below.

**Submitting Extramural Organizations:** Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

**Submitting Intramural DoD Organizations:** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.Gov or may submit to eBRAP. Applications from non-DoD...
organizations received through eBRAP will be withdrawn. See definitions in Section II.C.1., Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural Submissions: A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.

To begin the submission process, first select whether the organization is an extramural or intramural applicant, then confirm your selection or cancel. Incorrect selection of extramural or intramural submission type may result in delays in processing.

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

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 or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.
The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Tab 1 – Application Information**

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

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

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

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

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

  FY17 BMFRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to Section II.H.2.c., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Pre-Applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest (COIs)**

  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). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

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

  The Preproposal Narrative should include the following:

  - **Intent of the BMFRP Objectives:** Describe how the proposed research adheres to the intent of the BMFRP 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 FY17 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 PI and research team and how this will factor into their ability to successfully complete the proposed research. Articulate the eligibility of the PI as an EI or an ECI.

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

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

    - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
Key Personnel Biographical Sketches (five-page limit per individual). All biographical sketches should be uploaded as a single combined file. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- Tab 6 – Submit Pre-Application
  
  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- Pre-Application Screening Criteria
  
  To determine the technical merits of the pre-application and the relevance to the mission of the 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 diseases. How well the proposed research focuses on the FY17 BMFRP objective. 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 EI or as an ECI.
    - 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 time frame for notification of invitation to submit an application is indicated in Section I., Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless the PI has received notification of invitation.
All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See General Application Instructions, Section III, for details on compatible Adobe software.

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

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

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

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

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<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
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<tbody>
<tr>
<td><strong>Application Package Location</strong></td>
<td></td>
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<tr>
<td><strong>Full Application Package Components</strong></td>
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<tr>
<td><strong>SF424 (R&amp;R) Application for Federal Assistance Form:</strong> Refer to the General Application Instructions, Section III.A.1., for detailed information.</td>
<td><strong>Tab 1 – Summary:</strong> Provide a summary of the application information. <strong>Tab 2 – Application Contacts:</strong> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</td>
</tr>
</tbody>
</table>
| Descriptions of each required file can be found under Full Application Submission Components:  
- Attachments  
- Research & Related Senior/Key Person Profile (Expanded)  
- Research & Related Budget  
- Project/Performance Site Location(s) Form  
- R&R Subaward Budget Attachment(s) Form (if applicable) | **Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:  
- Attachments  
- Key Personnel  
- Budget  
- Performance Sites  
**Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form. |
<table>
<thead>
<tr>
<th>Extramural Submissions</th>
<th>Intramural DoD Submissions</th>
</tr>
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<tbody>
<tr>
<td><strong>Application Package Submission</strong></td>
<td><strong>Submit package components to <strong>eBRAP</strong> <em>(<a href="https://ebrap.org">https://ebrap.org</a>)</em>. Tab 5 – Submit/Request Approval Full Application:</strong> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.</td>
</tr>
<tr>
<td>Submit package components to Grants.gov <em>(<a href="http://www.grants.gov">http://www.grants.gov</a>)</em>. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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.</td>
<td></td>
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<tr>
<td><strong>Application Verification Period</strong></td>
<td><strong>Application Verification Period</strong></td>
</tr>
<tr>
<td>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, <em>with the exception of the Project Narrative and Budget Form</em>, may be modified.</td>
<td>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, <em>with the exception of the Project Narrative and Budget Form</em>, may be modified.</td>
</tr>
<tr>
<td><strong>Further Information</strong></td>
<td><strong>Further Information</strong></td>
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<tr>
<td>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</td>
<td>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</td>
</tr>
</tbody>
</table>

*The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.*

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. *The Project Narrative and Budget cannot be changed after the application submission deadline.* Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

*Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.*
The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- Extramural Applications Only –

  **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1., for detailed information.

- Extramural and Intramural Applications –

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

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

  - **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) 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 include the information required in **Section II.B., Award Information**.

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

    - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

    - **Specific Aims:** Concisely explain the project’s specific aims. If this research project is part of a larger study, present only the tasks that this award would fund.
**Research Strategy:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). 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, or 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.** Combine and upload as a single file named “Support.pdf.” Start each document on a new page. If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

*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 result in the removal of those items or may result in administrative withdrawal of the application.*

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

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether 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 Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five
published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from Members of Congress, do not impact application review or funding decisions.

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

  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

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

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

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

Impact: Summarize how the proposed project is relevant to and will have an impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be particularly impacted by the research.

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

- Background and 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.

- The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:
  - Include the name(s) of the key personnel and contact information for each study site/subaward site.
  - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site.
Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

- Briefly state the methods to be used.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

- **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 BMF 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: Early Career Investigator Eligibility Statement, if applicable (one-page limit).** Upload as “ECIeligibility.pdf.” Use the Early Career Investigator Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met. For more eligibility details, refer to Section II.B., Award Information, and Section II.C., Eligibility Information.
Attachment 9: DoD Military 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 DoD Military Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7., for detailed information.

Extramural and Intramural Applications –

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

- 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 the portable document format (pdf) that is not editable.

- 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.”

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

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

Project/Performance Site Location(s) Form: For detailed information regarding extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5., and regarding intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4.
• **Extramural Applications Only –**

**R&R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.6., for detailed information.

  o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6., for detailed information.)
  
  o **Intramural DoD Collaborators:** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 9. (Refer to the General Application Instructions, Section III.A.7., for detailed information.)

Subaward costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

**II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)**

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. Verify the status of the applicant’s organization’s Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

**II.D.4. Submission Dates and Times**

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

**Applicant Verification of Full Application Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

The maximum period of performance is 2 years.

The anticipated direct costs budgeted for the entire period of performance will not exceed $315,000. If direct costs have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $315,000 direct costs or using an indirect rate exceeding the organization’s negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years.

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

- Salary
- Research supplies
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 2 investigators to travel to 1 scientific/technical meeting per year

Must not be requested for:

- Clinical trial costs

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental-only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency’s procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.4., for budget regulations and instructions for the Research & Related Budget. For Federal agencies or organizations
collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4.

The CDMRP expects to allot approximately $2.6M of the $3M FY17 BMFRP appropriation to fund approximately five (5) Idea Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of federal funds for this program.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Research Strategy and Feasibility**
  - To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, published data, BMF-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 aims, experimental design, methods, and analyses are developed and integrated into the project.
  - To what degree the research design and methods can successfully achieve the goals of the proposed project.
  - To what extent the 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**
  o 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.
  o To what degree the potential level of gain for the research community or patient community justifies the risk of the proposed research project.
  o 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**
  o 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.
  o 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.
  o How well the anticipated long-term gains from this research will yield relevant results for BMF research or patient care.

• **Personnel**
  o For EIs only:
    - Whether the PI meets the eligibility requirements as an EI.
    - 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.
  o For ECIs only:
    - Whether the PI meets the eligibility requirements as an ECI.
    - Whether the PI’s previous training (postdoctoral or clinical) supports the abilities of the ECI to accomplish the proposed work.
    - Whether the institution, through its Letter(s) of Organizational Support, has demonstrated commitment (i.e., independent laboratory space, funding) to establish a career for the ECI in BMF research.
– 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:

**Budget**

- Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.
- Whether there is significant overlap with existing or pending awards of the PI, as demonstrated by the PI’s Biosketch and Previous/Current/Pending Support document.

**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.

**Application Presentation**

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

**II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and BMFRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact and innovation with respect to the FY17 BMFRP objective
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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and BMFRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. 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 http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a 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 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 (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant’s integrity, business ethics, and record of performance under Federal awards when determining a recipient’s qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), section 22.415.
II.E.4. Anticipated Announcement and Federal Award Dates

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

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

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

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Funding to Federal Government organizations (to intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are
reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI’s organization.

II.F.1.a. Award Transfers

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

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

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

Refer to full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

In addition to written progress reports, Annual Award Charts will be required. For the BMFRP Idea Development Award mechanism, use the format example titled, “Generic Award Charts,” available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm).

Awards resulting from this Program Announcement will incorporate 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 $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-
year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the 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

II.G.2. Grants.gov Contact Center

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

Phone: 800-518-4726; International 1-606-545-5035
Email: support@grants.gov

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

II.H. Other Information

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170418a. The Program Announcement numeric version code will match the General Applications Instructions version code 20170418.
II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

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

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY17 BMFRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY17 BMFRP Programmatic Panel members can be found at http://cdmrp.army.mil/bmfrp/panels/panels17.
- The application fails to conform to this Program Announcement 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.
To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.

Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds as subawards or subcontracts to extramural collaborators.

The invited application does not propose the same research project described in the pre-application.

If a clinical trial is proposed, the application will be withdrawn.

If the PI does not meet the specified eligibility criteria, the application will be withdrawn.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.
## II.H.3. Application Submission Checklist

<table>
<thead>
<tr>
<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424 (R&amp;R) Application for Federal Assistance (Extramural submissions only)</td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)</td>
<td>Complete these tabs as instructed.</td>
<td></td>
</tr>
<tr>
<td>Attachments</td>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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<tr>
<td></td>
<td>Lay Abstract: Upload as Attachment 4 with file name “LayAbs.pdf.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Impact Statement: Upload as Attachment 6 with file name “Impact.pdf”</td>
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</tr>
<tr>
<td></td>
<td>Innovation Statement: Upload as Attachment 7 with file name “Innovation.pdf”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Early Career Investigator Eligibility Statement: Upload as Attachment 8 with file name “ECIeligibility.pdf,” if applicable.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DoD Military Budget Form(s): Upload as Attachment 9 with file name “MFBudget.pdf,” if applicable.</td>
<td></td>
</tr>
<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Research &amp; Related Budget (Extramural submissions only)</td>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Budget (Intramural submissions only)</td>
<td>Complete the DoD Military Budget Form and justification.</td>
<td></td>
</tr>
<tr>
<td>Project/Performance Site Location(s) Form</td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>R&amp;R Subaward Budget Attachment(s) Form, if applicable</td>
<td>Complete form as instructed.</td>
<td></td>
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</tbody>
</table>
### APPENDIX 1: ACRONYM LIST

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACURO</td>
<td>Animal Care and Use Review Office</td>
</tr>
<tr>
<td>BMF</td>
<td>Bone Marrow Failure</td>
</tr>
<tr>
<td>BMFRP</td>
<td>Bone Marrow Failure Research Program</td>
</tr>
<tr>
<td>CDMRP</td>
<td>Congressionally Directed Medical Research Programs</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>DHA</td>
<td>Defense Health Agency</td>
</tr>
<tr>
<td>DHP</td>
<td>Defense Health Program</td>
</tr>
<tr>
<td>DoD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>DoDGAR</td>
<td>Department of Defense Grant and Agreement Regulations</td>
</tr>
<tr>
<td>DUNS</td>
<td>Data Universal Numbering System</td>
</tr>
<tr>
<td>eBRAP</td>
<td>Electronic Biomedical Research Application Portal</td>
</tr>
<tr>
<td>EC</td>
<td>Ethics Committee</td>
</tr>
<tr>
<td>ECI</td>
<td>Early Career Investigator</td>
</tr>
<tr>
<td>EI</td>
<td>Established Investigator</td>
</tr>
<tr>
<td>ET</td>
<td>Eastern Time</td>
</tr>
<tr>
<td>FY</td>
<td>Fiscal Year</td>
</tr>
<tr>
<td>HRPO</td>
<td>Human Research Protection Office</td>
</tr>
<tr>
<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>M</td>
<td>Million</td>
</tr>
<tr>
<td>OASD(HA)</td>
<td>Office of the Assistant Secretary of Defense for Health Affairs</td>
</tr>
<tr>
<td>OMB</td>
<td>Office of Management and Budget</td>
</tr>
<tr>
<td>ORP</td>
<td>Office of Research Protections</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RDT&amp;E</td>
<td>Research, Development, Test, and Evaluation</td>
</tr>
<tr>
<td>RM</td>
<td>Resource Manager</td>
</tr>
<tr>
<td>SAM</td>
<td>System for Award Management</td>
</tr>
<tr>
<td>SOW</td>
<td>Statement of Work</td>
</tr>
<tr>
<td>USAMRAA</td>
<td>U.S. Army Medical Research Acquisition Activity</td>
</tr>
<tr>
<td>USAMRMC</td>
<td>U.S. Army Medical Research and Materiel Command</td>
</tr>
<tr>
<td>USC</td>
<td>United States Code</td>
</tr>
</tbody>
</table>