

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

New Investigator Award

Funding Opportunity Number: W81XWH-10-BMFRP-NIA

TABLE OF CONTENTS

I.	Funding Opportunity Description.....	2
A.	Program Description.....	2
B.	Award Description	2
C.	Eligibility.....	3
D.	Funding.....	3
E.	Award Administration.....	4
II.	Timeline for Submission and Review.....	4
III.	Submission Process	4
A.	Step 1 – Pre-Application Components	4
B.	Step 2 – Application Components.....	6
IV.	Information for Application Review	9
A.	Application Review and Selection Overview	9
B.	Review Criteria.....	10
V.	Administrative Actions.....	12
VI.	Contact Information	14
VII.	Application Submission Checklist.....	15

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Appropriations History: The Bone Marrow Failure Research Program (BMFRP) was established in fiscal year 2008 (FY08) to promote innovative research focused on bone marrow failure (BMF). Appropriations for the BMFRP from FY08 through FY09 totaled \$6 million (M). The FY10 appropriation is \$3.75M.

FY10 Objectives: The objectives of the BMFRP are to fund scientifically meritorious research focused on BMF syndromes and their long-term sequelae. Studies that primarily focus on myeloproliferative neoplasms, leukemia, or other malignancies are discouraged. However, studies investigating BMF syndromes and their progression to other malignancies such as leukemia are acceptable. Proposals involving therapeutics, including but not limited to bone marrow transplantation, are strongly encouraged to address issues unique to BMF syndromes.

The vision of the FY10 BMFRP is to understand and cure BMF disease. Toward that end, the program challenges the scientific community to design innovative research that will advance the understanding of inherited and acquired BMF diseases to improve the health and life of individuals living with these diseases, with the ultimate goals of prevention and/or cure.

B. Award Description

The BMFRP New Investigator Award (NIA) mechanism is being offered for the first time in FY10.

The intent of the BMFRP NIA is to support the career transition and/or continued development of promising, independent, non-mentored investigators, who are in the early stages of their scientific careers, in the field of BMF disease research. Principal Investigators (PIs) should have a strong desire to pursue a career as a BMF researcher and demonstrate the potential for a successful career focused on BMF research. ***Experience in BMF research is not required.*** PIs with a limited background in BMF research are strongly encouraged to include a collaborator who is experienced and has published in the field of BMF research. Additionally, the research proposed by the PI should include innovative ideas and approaches with the potential for high impact to meet the objectives of the FY10 BMFRP.

Clinical trials are not allowed. Research involving human subject use is permitted under this funding opportunity, but is restricted to studies without clinical trials. The FY10 BMFRP is not offering an award mechanism that will support clinical trials.

The following are significant features of the proposed research project:

- 1. Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely 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.

2. **Impact:** Research that has high impact will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, and/or treatment of BMF.
3. **Preliminary Data:** Preliminary data, unpublished results from the laboratory of the PI or collaborators named on this application, and/or data from the published literature, that is relevant to BMF and the proposed research project should be included. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

C. Eligibility

Independent, non-mentored PIs at the level of Assistant Professor (or equivalent) with no more than six years at his/her current academic level at the time of the application submission deadline are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is **\$400,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs (clinical trials will not be supported)
- Travel between collaborating institutions
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.4 M of the \$3.75M FY10 BMFRP appropriation to fund approximately four New Investigator 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.

E. Award Administration

Changes in PI will not be allowed. Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 11, 2010**
- **Invitation to Submit an Application: April 27, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, June 10, 2010**
- **Scientific Peer Review: July 2010**
- **Programmatic Review: October 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). *Applications will be invited based on pre-application screening.*

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

PIs and organizations identified in the application should be the same as those identified in the pre-application.

No change in PI will be allowed after the pre-application deadline. If a change in organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by *5:00 p.m. ET on the deadline. Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.*

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs: (Refer to the General Application Instructions for additional information on pre-application submission.)

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest– Tab 3**
- **Required Files – Tab 4**

Preproposal Narrative (two-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research:** 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:** Describe the potential impact of this study on BMF and how it may significantly advance the understanding of inherited and acquired BMF diseases; to improve the health and life of individuals living with these diseases.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- **References Cited (one-page limit):** List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
- **Key Personnel Biographical Sketches (four-page limit per individual)**
- **BMF Career Plan (one-page limit):** Briefly discuss current and future career plans that highlight a strong desire to pursue a career as a BMF researcher and potential for a successful career focused on BMF research including the following:
 - Commitment to pursuing a career in BMF research
 - Long-term career goals, and how these would be affected by receiving this award
 - Qualifications, characteristics, and achievements that indicate a strong potential for success as a BMF researcher

- Description of current scientific environment, and how it will facilitate career goals
- o Two Letters of Recommendation: Each letter should be signed and should include a description of the PI's qualifications, characteristics, and accomplishments that highlight his/her potential for success in pursuing a career focused on BMF research. In addition, the writer should provide his/her perspective on the PI's commitment for establishing a successful career in BMF research.
- **Submit Pre-application – Tab 5**
- **Other Documents Tab**
Not applicable

Pre-Application Screening: Pre-applications will be screened by the FY10 BMFRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **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.
- **Impact:** Whether the proposed research, if successful, will make an important contribution that significantly advances the prevention, detection, diagnosis, and/or treatment of BMF.
- **BMF Career Plan:** Whether the PI is committed to pursuing a career in BMF research and has credentials indicating potential for success in this field.
- **Research Idea:** How well the proposed project addresses a central critical problem or question in BMF research.

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

Applications will not be accepted unless the PI has received a letter of invitation.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

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

2. Attachments Form

- **Attachment 1: Project Narrative (6-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work; include relevant literature citations. Describe previous experience most pertinent to this application. Preliminary data, unpublished results from the laboratory of the PI or collaborators named on this application, and/or data from the published literature that is relevant to BMF and the proposed research project should be included.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this application. If this proposal is part of a larger study, present only tasks that the DOD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*
- **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. *Each component has no page limit unless otherwise noted.*
 - **References Cited :** List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
 - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - **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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
Describe the proposed research project including the following elements: background, hypothesis or objective, study design, and the relevance of the project to BMF research.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Clearly describe, in a manner readily understood by lay persons, the central critical problem or question to be addressed, the innovative aspect of the research, and the relevance of the project to BMF research.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 8: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.” Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.

Although not all-inclusive, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new

technologies, including technology development, to address a research question.

- Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treating.
- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- **Attachment 9: Impact Statement (one-page limit):** Uploaded as “Impact.pdf.” Explain why the proposed research project is important and relevant to BMF disease. *Describe the short-term impact:* Detail the anticipated outcome(s)/ product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research. *Describe the long-term impact:* Explain the anticipated long-term gains from this research course and compare to information/products currently available, if applicable. Articulate the long-term anticipated advantages to understanding the causes and progression of disease, and/or to the development of new diagnostic or treatment options.

3. Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

4. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and 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 review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-

disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria. The PI is the most important individual criterion, while the others are of equal importance.

- **Principal Investigator**
 - How the PI meets the intent of this award mechanism.
 - How well the PI demonstrates an understanding of the disease and clearly articulates the studies to be conducted through the proposal.
 - Appropriateness of the levels of effort by the PI and other key personnel to ensure the success of this project.
 - Whether the applicant meets the eligibility requirements.
- **Innovation**
 - How well the research proposes new paradigms or challenges existing paradigms.
- **Impact**
 - How the proposed work addresses a critical problem in BMF research or patient care.
 - How the research, if successful, will make an original and important contribution toward understanding and curing BMF disease.
 - How well the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) are described.
 - How well the anticipated long-term gains from this research course are described and compared to information/products currently available, if applicable.
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, BMF-relevant preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods,

and analyses are developed and integrated into the project.

- How well the PI acknowledges potential problems and addresses alternative approaches.
- Whether the proposal includes an appropriate statistical plan with power analysis, if applicable.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
 - How the research team's background and BMF-related expertise are appropriate to accomplish the proposed work.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **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.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations.

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative innovation and impact

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt 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.
- PI Biosketch is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not received.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 BMFRP Integration Panel (IP) member(s) is found to be involved in the preapplication or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY10 BMFRP IP members may be found at <http://cdmrp.army.mil/bmfrp/panel10>
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The proposed research is or contains a clinical trial.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- PI is not the PI listed in the pre-application.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
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/Funding Opportunity. If the 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	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1	
	Upload Supporting Documentation (Support.pdf) as Attachment 2	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Innovation Statement (Innovation.pdf) as Attachment 8	
	Upload Impact Statement (Impact.pdf) as Attachment 9	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field	
	Attach PI 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 Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field	
Project/Performance Site Location(s) Form	Complete form as instructed	