

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-10- BMFRP-EHDA

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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 Exploration – Hypothesis Development Award was first offered in FY09. Of the 80 EHDA applications that were received, 7 were recommended for funding.

This award supports the initial exploration of innovative, untested, novel, and potentially groundbreaking concepts in bone marrow failure research. Results of studies conducted through this award may provide the scientific rationale upon which a new hypothesis can be based, or provide initial principles of an innovative hypothesis. Because this award is designed to provide investigators with the opportunity to pursue serendipitous observations, some gaps in the supporting rationale may exist due to lack of available information. The award mechanism is not intended to support the continuation of existing studies.

Inclusion of preliminary data is discouraged. The existence of substantial preliminary data suggests that the proposed research does not meet the intent of this award mechanism and would be more appropriately submitted elsewhere.

Use of human subjects and human biological substances: Projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Additional information regarding exempt status may be found on the following web sites <https://mrmc.amedd.army.mil/rodorphrpo.asp>, and [https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/\\$file/Title_32_CFR_Part_219.pdf](https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/$file/Title_32_CFR_Part_219.pdf).

C. Eligibility

All Investigators are eligible to submit applications. Refer to General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 18 months.
- The maximum allowable funding for the entire period of performance is **\$100,000** in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 18-month 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
- 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 \$900,000 of the \$3.75M FY10 BMFRP appropriation to fund approximately 6 Exploration – Hypothesis Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Changes in PI will not be allowed. Changes in organization are discouraged and will be allowed only at the discretion of the USAMRMC Contracting Office. 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 25, 2010
- **Application Submission Deadline:** 11:59 p.m. ET, April 8, 2010
- **Scientific Peer Review:** June 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/>).

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. 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*.

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**

Letter of Intent (LOI) Narrative (one-page limit): Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only (e.g., reviewer recruitment) and *will not be reviewed* during either the peer or programmatic review sessions.

- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

Not applicable.

B. Step 2 – Application Components

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

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

Reviewers will be blinded to the identity of the PI and the PI's organization. Due to the blinded nature of the review process, identifying or making references to the PI or the organization in the Project Narrative, Public and Technical Abstracts, or List of Acronyms and Symbols is prohibited and will result in administrative rejection of the proposal. In addition, the use of “I,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, and/or organization through the references listed will result in administrative rejection of the proposal.

- **Attachment 1: Project Narrative (3-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below. The presentation of preliminary data is discouraged. The existence of substantial preliminary data suggests that the research would be more appropriately submitted to a different award mechanism.

Innovation: Innovative projects may propose new paradigms or challenge existing paradigms. 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 prevention, detection, diagnosis, or treatment.
- Novel applications of 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.

Significance/Relevance: Provide a brief statement in nontechnical terms regarding the importance of this work to bone marrow failure research and/or patient care.

Rationale/Purpose: State the rationale/purpose for the proposed research.

Objectives: State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study.

Methods: Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. This award may not be used to conduct clinical trials or studies involving human subjects or specimens that are not exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).

- **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 (No 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.
 - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Briefly describe the proposed research including the objectives, the innovative aspect of the research, and the relevance of the project to BMF disease.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.” Briefly describe, in a manner readily understood by lay persons, the innovative aspect of the research and the relevance of the project to BMF disease.
- **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.

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.

Although requested, the Statement of Work, Detailed Budget and Justification, Subaward Detailed Budget and Justification (if applicable), Biographical Sketch and Project/Performance Site Location(s) Form will not be forwarded for peer or programmatic review. These documents will be used for administrative purposes only.

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> Reviewers will be blinded to the identity of the PI and the PI’s organization.

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 nondisclosure 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, which are of equal importance:

- **Innovation**
 - How the proposed research is innovative.
 - How the project proposes new paradigms or challenges existing paradigms.
 - How the proposed research represents more than an incremental advance.
- **Significance/Relevance**
 - How the study is significant/relevant to the field of bone marrow failure research and/or patient care.
- **Methods**
 - How the experimental design and methodology are appropriate to answer the question posed by the rationale/purpose.

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

- **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
- Ratings and evaluations of the peer reviewers
- Relative innovation

V. ADMINISTRATIVE ACTIONS

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

A. Rejection

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).
- Pre-application is not submitted.
- PI or collaborator name(s) or institution is included in the Project Narrative, Technical and Public Abstracts, or List of Acronyms and Symbols.
- Use of “I,” “our,” “this institution,” or similar phrases in the Project Narrative, Public and Technical Abstracts, or List of Acronyms and Symbols that make it possible to identify the PI, collaborators, and/or organization.

B. Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project 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.
- Studies not exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).

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	
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	