

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Exploration – Hypothesis Development Award

Funding Opportunity Number: W81XWH-09-BMFRP-EHDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Bone Marrow Failure Research Program (BMFRP) was established in fiscal year 2008 (FY08) with a \$1 million (M) appropriation to promote innovative research focused on bone marrow failure (BMF). The FY09 appropriation for the BMFRP is \$5M.

The BMFRP challenges the scientific community to design innovative research that will advance the understanding of inherited and acquired bone marrow failure diseases; to improve the health and life of individuals living with these diseases, with the ultimate goal of finding cures.

B. Award Description

The BMFRP Exploration – Hypothesis Development Award is being offered for the first time in FY09.

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 it should 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 supporting rationale may exist due to lack of available information. The award mechanism is not intended to support ongoing work. ***The presentation of preliminary data is not required.*** The existence of substantial preliminary data suggests that the research would be more appropriately submitted to a different award mechanism.

Clinical trials will not be supported under this award mechanism. Refer to the Application Instructions, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

Use of human subjects and human biological substances: Because these awards are designed for preliminary investigations, 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). Studies that do not qualify for exempt or expedited status during review at any level will be administratively withdrawn and will not be funded. For studies using only commercially available or de-identified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphrpo.asp>).

C. Eligibility

Principal Investigators (PIs) at all academic levels (or equivalent) are eligible to submit applications. Refer to Application Instructions and General Information, 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 your institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.0M of the \$5M FY09 BMFRP appropriation to fund approximately seven Exploration-Hypothesis Development Award applications, depending on the quality and number 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

No change in PI will be allowed once the application has been submitted. Changes in institution are discouraged and will be allowed only at the discretion of the USAMRMC Contracting Office. Refer to the Application Instructions, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

Pre-application Submission Deadline:	July 9, 2009
Application Submission Deadline:	July 30, 2009
Scientific Peer Review:	August 2009
Programmatic Review:	November 2009

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/), and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 – Pre-Application Components and Submission

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time (ET) on the deadline date**. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2 – Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, references to the PI or the institution in the Project Narrative, Public Abstract, and Technical Abstract are prohibited and will result in administrative withdrawal of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed will result in administrative withdrawal of the application.

Although requested, the Statement of Work (SOW), Detailed Budget and Justification, Federal Agency Financial Plan (if applicable), Subaward Detailed Budget and Justification (if applicable), and Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. These documents will be used for administrative purposes only.

- **Attachment 1: Project Narrative (Three-page limit)**

Describe the proposed project in detail using the outline below. The presentation of preliminary data is not required. The existence of substantial preliminary data suggests that the research would be more appropriately submitted to a different award mechanism.

Innovation: Innovation should be the primary feature of the proposed study. 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.

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**

- References Cited
- Acronyms and Symbol Definitions

- **Attachment 3: Technical Abstract (One-page limit)**

- **Attachment 4: Public Abstract (One-page limit)**

- **Attachment 5: Statement of Work (Three-page limit)**

- **Attachment 6: Detailed Budget and Justification**

Although requested, the Detailed Budget and Justification will not be forwarded for review due to the blinded nature of each level of review for this award. The Detailed Budget and Justification will be used for administrative purposes only.

- **Attachment 7: Federal Agency Financial Plan (if applicable)**

Although requested, the Federal Agency Financial Plan will not be forwarded for review due to the blinded nature of each level of review for this award. The Federal Agency Financial Plan will be used for administrative purposes only.

- **Attachment 8-14: Subaward Detailed Budget and Justification (if applicable)**

Although requested, the Subaward Detailed Budget and Justification will not be forwarded for review due to the blinded nature of each level of review for this award. The Subaward Detailed Budget and Justification will be used for administrative purposes only.

3. Research & Related Senior/Key Person Profile (Expanded Form)

PI Biographical Sketch (Four-page limit)

Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. The Biographical Sketch will be used for administrative purposes only.

4. Research & Related Project/Performance Site Location(s) Form

Although requested, the Research & Related Project/Performance Site Location(s) Form will not be forwarded for review due to the blinded nature of each level of review for this award. The Research & Related Project/Performance Site Location(s) Form 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 submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions 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 listed in decreasing order of 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 criterion 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.

Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism
- Program portfolio balance
- Ratings and evaluations of the peer reviewers
- Relative innovation

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel members and recommended for funding to the Commanding General, USAMRMC.

The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals and objectives of the program.

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.
- PI's name or institution is included in the Project Narrative.
- Use of "I," "our," "this institution," or similar phrases in the Project Narrative, Public Abstract, and Technical Abstract that make it possible to identify the PI and/or institution through the references listed.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. Eastern Time on the second full business day following the date the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application 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 FY09 BMFRP IP members may be found at <http://cdmrp.army.mil/research>
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- 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 USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. 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
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

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

Phone: 301-682-5507
Website: <https://cdmrp.org>
Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the [Grants.gov](http://www.grants.gov) ([http://www.grants.gov/](http://www.grants.gov)) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726,
Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.