

Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Idea Award

Funding Opportunity Number: W81XWH-09-BMFRP-IA

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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 Idea Award mechanism is being offered for the first time in FY09.

This award is intended to support innovative ideas and high-impact approaches to bone marrow failure research to move toward the BMFRP vision of understanding and curing bone marrow failure disease. This award mechanism is designed to support new ideas, not ideas that are extensions of existing work. Proposals should have a high probability of revealing new avenues of investigation.

NOTE: Clinical trials will not be supported under this mechanism. Refer to the Application Instructions and General Information, Appendix 6, for additional information about clinical trials.

The BMFRP seeks applications from all areas of basic, translational, and epidemiological research. The following are significant features of this award mechanism:

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 bone marrow failure research, provided that there is the potential for significant impact on the field of research and/or patient care. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.

Examples of research that is *not* innovative and will *not* be considered for funding under this award mechanism include, but are not limited to:

- Proposing research that is merely the next logical step or obvious incremental advancement
- Using a published series of *in vitro* assays to further characterize a model system
- Incorporating known biomarkers into *in vitro* or clinical models of bone marrow failure.

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 bone marrow failure.

3. Preliminary Data: Preliminary data, unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application, and/or data from the published literature, that is relevant to bone marrow failure 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

Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications.

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance for this award mechanism is **3** years.
- The maximum allowable funding for the entire period of performance is **\$375,000** for 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 your institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs (Clinical trials will not be supported)
- Travel between collaborating institutions
- Travel to scientific/technical meetings
- Other direct costs as described in Application Instructions & General Information

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.1M of the \$5M FY09 BMFRP appropriation to fund approximately two Idea 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 on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Submission is a two-step process consisting of (1) pre-application submission and (2) application submission. *Pre-application submission is a required first step.*

| | |
|---|--|
| Pre-application Submission Deadline: | September 22, 2009, 5:00 p.m. Eastern Time (ET) |
| Invitation to Submit a Proposal: | November 18, 2009 |
| Application Submission Deadline: | January 14, 2010, 11:59 p.m. ET |
| Scientific Peer Review: | March 2010 |
| Programmatic Review: | April 2010 |

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

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/). *Applications will be invited based on pre-application screening.*

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

A. Step 1 – Pre-Application Components, Submission, and Screening

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. ET on the pre-application deadline.*

The PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. The PI will be assigned a log number by the CDMRP eReceipt system. The PI must submit his or her Grants.gov application package using

only his or her log number. If there is a change in PI or organization after the submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507. In addition to the award-specific instructions below, refer to the Application Instructions for detailed information on pre-application components and submission.

- **Proposal Information:** 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.
- **Proposal Contacts**
- **Collaborators and Conflicts of Interest (COI)**
- **Preproposal Narrative:** The Preproposal Narrative has a *two-page limit* inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preapplication. 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 bone marrow failure and how it may significantly advance the understanding of inherited and acquired bone marrow failure 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:
 - References Cited: (one-page limit)
 - Biographical Sketches: Include biographical sketches for the PI and key collaborators. (four-page limit per biosketch)

Pre-Application Screening: Pre-applications will be screened by the FY09 BMFRP Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Adherence to the intent of the award mechanism**
- **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 bone marrow failure.
- **Research Idea:** How well the proposed project addresses a central critical problem or question in bone marrow failure research.

B. Step 2 – Application Components and Submission

Applications will not be accepted unless the PI has received a letter of invitation. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). The PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application.

Each application submission must include the completed Grants.gov 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.

Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or focus area(s).

The package includes:

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

2. Attachments Form

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

Describe the proposed project in detail using the following outline.

Background: Present the ideas and reasoning behind the proposed research; 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 bone marrow failure 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.

Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls and statistical plan, in sufficient detail for analysis. Include specific examples of innovative elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials.*

- **Attachment 2: Supporting Documentation**

- References Cited
- Acronyms and Symbol Definitions
- Facilities & Other Resources
- Description of Existing Equipment
- Publication URLs and/or Patent Abstracts (five-document limit)
- Letters of Institutional Support

If the PI is a clinician, the institution must clearly demonstrate a commitment to the clinician's research.

- Letters of Collaboration (if applicable)
- Intellectual and Material Property Plan (if applicable)

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

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

- **Attachment 5: Statement of Work (SOW; three-page limit)**

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

- **Attachment 7: Innovation Statement (one-page limit)**

Summarize how the proposed work is innovative. Describe how the research represents more than an incremental advance on published data.

Although not all-inclusive, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame 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.
- 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 8: Impact Statement (one-page limit)**

Describe how the proposed work and expected results will, if successful, have an impact on understanding and curing bone marrow failure disease and advancing research on the prevention, detection, diagnosis, and/or treatment of BMF.

- **Attachment 9: Federal Agency Financial Plan (if applicable)**
- **Attachments 10-15: Subaward Detailed Budget and Justification (if applicable)**

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches
- Key Personnel Current/Pending Support

4. Project/Performance Site Location(s) Form

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.htm>.

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. Correspondingly, 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).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement).

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 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.
 - How the proposed research project is a new research idea and not the next logical step or continuation of a previous research project.
 - How the proposed research represents more than an incremental advance upon published data.
- **Impact**
 - How the project, if successful, will make an original and significant contribution to bone marrow failure research.
 - How the project, if successful, will advance the BMFRP goals of conquering bone marrow failure and advancing research on the prevention, detection, diagnosis, and/or treatment of bone marrow failure.
- **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, bone marrow failure-relevant preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, specific 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 criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
 - Whether the applicant meets the eligibility requirements.
 - How the research team's background and bone marrow failure-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 the award mechanism.
- **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 that maintain the program’s broad portfolio:

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

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 pre-applications from 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.
- 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 for all documents other than the Preproposal Narrative or Project Narrative.
- Documents not requested will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by the 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. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- The proposed research project is or contains a clinical trial.
- Submission of an application for which a letter of invitation was not received.
- Any FY09 BMFRP IP member 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/bmfrp/panel09.htm>.
- 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.

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/>) 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. The deadline for application submission is 11:59 p.m. ET on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please note 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.