

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Bone Marrow Failure Research Program

Idea Development Award

Funding Opportunity Number: W81XWH-14-BMFRP-IDA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), May 13, 2014
- **Invitation to Submit an Application:** June, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, August 28, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, September 2, 2014
- **Peer Review:** October 2014
- **Programmatic Review:** December 2014

Change for Fiscal Year 2014: *The CDMRP eReceipt System has been replaced with the Electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to peer review.*

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2014 (FY14) Bone Marrow Failure Research Program (BMFRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The BMFRP was established in FY08 to promote innovative research focused on BMF. Appropriations for the BMFRP from FY08 through FY13 totaled \$20.15 million (M). The FY14 appropriation is \$3.2M.

The vision of the BMFRP is to understand and cure BMF diseases. Toward that end, the program challenges the scientific community to design innovative research approaches based on sound scientific evidence that will advance the understanding of inherited and acquired BMF diseases to improve the health of individuals, with the ultimate goals of prevention and cure.

FY14 BMFRP Objective: The objective of the FY14 BMFRP is to fund scientifically meritorious research focused on BMF diseases and their long-term sequelae. Investigator-initiated research is encouraged in the areas of congenital or acquired BMF. Studies focused on BMF diseases and their progression to other malignancies such as leukemia are acceptable. *However, research primarily focused on myeloproliferative neoplasms, leukemia, or other malignancies is discouraged.* Projects including bone marrow transplantation or stem cell biology should address issues unique to BMF diseases.

B. Award Information

The BMFRP Idea Development Award is intended to support innovative ideas and high-impact approaches based on scientifically sound evidence to move toward the BMFRP vision of understanding and curing BMF diseases. This award mechanism is designed to support new ideas. Proposed research studies should have a high probability of revealing *new* avenues of investigation. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale and a developed and well-articulated research approach. Personnel on the proposed team should have a strong background in BMF research.

The following are significant features of this award mechanism:

- 1. Research Approach:** The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of BMF. Experimental strategies may be novel or may be based on strong rationale derived from previously published data, presented preliminary data, or literature review. The feasibility of the research design and methods should be well defined and a clear plan should be articulated in that the proposed goals of the project can successfully be achieved. Additionally, resources should be identified and supported through documentation. Identification of potential problems and pitfalls are strongly encouraged with alternate approaches addressed. A statistical analysis of the proposed research should be included if applicable as well as a power analysis to support the design and sample size.

2. **Preliminary Data:** Preliminary data such as unpublished results from the laboratory of the Principal Investigator (PI) or collaborators named on this application and/or data from the published literature relevant to BMF and the proposed research project may be included but are not required. If preliminary data are not included, the proposed research should be based on a strong rationale with sound logical support from published literature.
3. **Innovation:** Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. This may include high-risk, potentially high-gain, approaches to BMF research, provided that there is the potential for significant impact on the field of research, and/or patient care and/or quality of life. Research that is merely an incremental advance is *not* considered innovative.
4. **Impact:** Proposed research projects should address a central critical issue or question in BMF research or clinical care. High-impact research will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, and/or treatment of BMF.
5. **Personnel:** Personnel are considered a crucial part of the BMFRP Idea Development Award. The application should demonstrate the BMF expertise through the PI's background, research team or through collaboration. Collaborations should be documented.

Use of Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

Clinical trials are not allowed. A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. The FY14 BMFRP is not offering an award mechanism that will support clinical trials; PIs requesting funding for a clinical trial are encouraged to investigate other funding agencies for support. Additional information may be found at <https://ebrap.org/eBRAP/public/Program.htm> and in the General Application Instructions, Appendix 6.

The types of awards made under this Program Announcement/Funding Opportunity will be assistance agreements. Reference the General Application Instructions, Appendix 4, for additional information regarding award types.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section L.

C. Eligibility Information

- Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$400,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. *For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.*

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies

- Clinical research costs (*This award may not be used to conduct clinical trials.*)
- Support for multidisciplinary collaborations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Extramural investigators are defined as all those not included in the definition of intramural investigators. As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. *In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural investigator.*

The CDMRP expects to allot approximately \$2.56M of the \$3.2M FY14 BMFRP appropriation to fund approximately four Idea 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.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

New for FY14: *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and

affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-BMFRP-IDA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**

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

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 BMFRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Required Files – Tab 4**

Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

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

The Preproposal Narrative should include the following:

- **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research. Outline any preliminary data to be included, if applicable. Describe how the proposed research adheres to the intent of the program award description.
- **Hypothesis or Objective:** State the hypothesis to be tested and/or the objective to be reached. Clearly articulate how the research addresses the goals of the BMFRP. State the project's specific aims.
- **Innovation:** Describe how the proposed research is innovative and how the research represents more than an incremental advance on published data.
- **Impact:** Explain the potential impact of the proposed research project and how it will, if successful, move the research field toward achieving the BMFRP's vision to understand and cure BMF diseases.
- **Personnel:** Clearly describe the BMF expertise of the research team and how this will factor into their ability to successfully complete the proposed research. Articulate the eligibility of the PI.

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

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

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (four-page limit per individual):** Include biographical sketches for the PI and other key collaborators.
- **Submit Pre-Application – Tab 5**
This tab must be completed for the pre-application to be accepted and processed.

Pre Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the BMFRP, pre-applications will be screened based on the following criteria:

- **Adherence to the intent of the award mechanism**
- **Research Idea:** How well the proposed project addresses a critical problem or question in BMF research. How well the proposed research focuses on FY14 BMFRP objectives. Whether any preliminary data included supports the research idea.
- **Innovation:** How well the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other creative qualities.
- **Impact:** To what degree the proposed research, if successful, will make an important contribution that significantly advances current methods and concepts toward the BMFRP vision of understanding and curing BMF diseases.
- **Personnel:**
 - Whether the PI meets the eligibility requirements.
 - To what degree the PI and research team’s backgrounds and BMF-related expertise are appropriate to successfully carry out the proposed research project.
- **Notification of Pre-Application Screening Results**
Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weakness) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Forms

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

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

application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification. The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period)*.

Grants.gov application package components: For the Idea Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

2. Attachments Form

- **Attachment 1: Project Narrative (eight-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

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

- **Specific Aims:** Concisely explain the project’s specific aims. If this research project is part of a larger study, present only the tasks that the DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Include specific examples of key elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If applicable, describe the statistical plan with appropriate power analysis and how it supports the sample size. Research projects may include preclinical studies in animal models and human subjects and human anatomical substances. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. ***This award may not be used to conduct clinical trials. Note: Impact and innovation should not be addressed in the Project Narrative (Attachment 1), but instead should be articulated in Attachments 6 and 7, respectively (see below).***
- **Attachment 2: Supporting Documentation.** 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. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
 - **References Cited:** List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
 - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
 - **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section L for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
The technical abstract is used by all reviewers. The technical abstract should address the following elements:
 - Background: Present the ideas and reasoning behind the proposed research.
 - Hypothesis/Objective: State the hypothesis/objective to be tested.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design, including the appropriate controls.
 - Innovation: Briefly describe the novel or paradigm shift proposed in the project and how it will yield critical discoveries, new avenues of investigation, or major advancements to prevent or cure BMF diseases.
 - Impact: Summarize how the proposed project is relevant to and will have an impact on those affected by BMF and/or the understanding of BMF diseases. Identify the specific BMF disease that will be particularly impacted by the research.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”
The lay abstract is used by all reviewers. Do not duplicate the technical abstract. Include an overview of the proposed research project that can be readily understood by lay persons. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.
 - Background, hypothesis, or objectives
 - The critical problem or question to be addressed by the proposed research project
 - Identify the specific BMF disease to be researched or the overarching problem to be addressed

- Innovative aspects of the proposed research project
- The impact that the proposed research project results might have on the field of BMF research and/or patient care in the short and/or long term.
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Idea Development Award mechanism, use the SOW format example titled “*SOW (Statement of Work) Generic Format.*” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Describe why the proposed research project is important to understanding the causes and progression of BMF and/or to realizing improvements in patient care and/or quality of life.

Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will directly result from the proposed research.

Describe the long-term impact: Explain the potential long-term impact of this study on the field of research and/or patient care. Describe the anticipated long-term gains from this research and compare these to BMF information/products currently available, if applicable.

- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

Summarize how the proposed work is innovative.

- Describe how the proposed research project introduces a new paradigm, challenges existing paradigms, or looks at existing problems or issues from a new perspective.
- Describe how the research represents more than an incremental advance on published data, or current work in the applicant’s laboratory.
- If the proposed research project is high-risk, explain the potential gain from accomplishing the work and finding the outcomes.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C.3., for detailed information. ***Note: Some of the items in this attachment may be made available for programmatic review.***

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

4. Research & Related Budget: Refer to the General Application Instructions, Section II.C.4., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

5. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.C.5., for detailed information.

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

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

E. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on (a) technical merit and (b) the relevance to the mission of the DHP and BMFRP and to the 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 process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

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

- **Research Strategy and Feasibility**
 - To what degree does the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, published data, BMF-relevant preliminary data (if applicable), and/or logical reasoning.
 - How well the hypotheses or objectives, specific aim, experimental design, methods, and analyses are developed and integrated into the project.

- To what degree the research design and methods can successfully achieve the goals of the proposed project.
- To what extent the PI identifies potential problems, pitfalls, and addresses alternative approaches.
- Whether the application includes an appropriate statistical plan with power analysis, if applicable. How well the described statistical plan will evaluate the results and if it is appropriate for the sample size according to the power analysis.
- Whether the application demonstrates the availability of resources such as tissue, data, or human subjects, if applicable.
- **Innovation**
 - 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.
 - To what degree the potential level of gain for the research community or patient community justifies the risk of the proposed research project.
 - To what extent the proposed research represents more than an incremental advance upon published data, or current research being performed in the applicant's laboratory.
- **Impact**
 - How the research project, if successful, will make an important contribution that significantly advances our understanding of the causes and/or the progression of BMF and/or improves patient care and/or quality of life.
 - To what degree the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) will yield relevant results for BMF research or clinical care.
 - How well the anticipated long-term gains from this research course will yield relevant results for BMF research or clinical care.
- **Personnel**
 - Whether the applicant meets the PI eligibility requirements.
 - To what degree the BMF-related expertise and background represented on the research team is appropriate to accomplish the proposed work.
 - To what extent the levels of effort are appropriate for successful conduct of the proposed work.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **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**
 - To what extent the writing, clarity, and presentation of the application components influence the review.
- 2. Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
- a. **Ratings and evaluations of the peer reviewers**
 - b. **Relevance to the mission of the DHP and FY14 BMFRP, as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Programmatic relevance to the objective
 - Program portfolio composition
 - Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP 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.

The following will result in administrative rejection of the application:

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

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY14 BMFRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14 BMFRP IP members can be found at <http://cdmrp.army.mil/bmfrp/panels/panels14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section J, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact/Transition Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/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 Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	