COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

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November 9, 2015

Department of Defense
U.S. Army Medical Research and Materiel Command
Dr. John Frazier Glenn
Principal Assistant for Research and Technology
Fort Detrick, MD 21702

Subject: Conflict of Interest Requirements

Dear Dr. Glenn,

The Council on Governmental Relations (COGR) is non-profit association of 190 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

We are writing on behalf of our member institutions to communicate our concerns related the administrative burden associated with the Conflict of Interest requirements in the General Application Instructions, Fiscal Years 2015/2016, Department of Defense Health Program, Congressionally Directed Medical Research Programs. For your convenience, we have attached a copy of the General Application Instructions and Broad Agency Announcement for Extramural Research, to inform our concerns.

We request that the COI requirements of USAMRMC Pages 22-23 of the attached instructions be modified in order to relieve applicant institutions of burdensome application requirements and allow the institutions to focus on managing actual conflicts of interest. **Article 2. Conflicts of Interest states "All conflicts of interest (COIs) or potential COIs must be disclosed with the proposal/application submission, along with a plan to resolve them. All COIs on the part of an organization or individual investigators that could bias the research project must be resolved prior to the award of a contract or assistance agreement. Refer to the General Submission Instructions, Appendix 1, for additional information."**

COGR requests that the requirement for disclosure of all conflicts of interest (COIs) or potential COIs at the proposal/application stage be removed from the Article. The wording as currently stated could lead one to believe that all conflicts must be eliminated, not just managed. As a model of an effective COI policy, we would encourage the review of NSF's policy which focuses on the institutional responsibility for assuring disclosure and management of COIs. If disclosure to USAMRMC is required, then we request the disclosure requirement be made just

prior to award for the following reasons:

- A large majority of the applications submitted do not result in being awarded. Requiring a burdensome disclosure process and the development of a management plan for a proposed project which may never be awarded is unnecessarily burdensome for the applicants
- In many cases the nature of the work proposed is what creates the conflict or potential conflict. If the award is not made there is no conflict to manage and therefore the effort to develop a management plan is wasted
- Often times, during the time between proposal submission and award, the nature of the potential conflict of interest changes. Disclosure and planning for oversight are better informed based on current information at the time of award.
- The proposal process is deadline driven and would force the development of a management plan to be constrained by the due date for the proposal. Conflict of Interest management plans providing proper oversight of the activity can be complex and require the input and time commitments of senior level officials. The quality of such oversight plans will be enhanced by having the time necessary to develop proper oversight controls without the pressure of a proposal deadline.

In addition, for consistency with other Federal Agency policies we request the term "institution" be replaced with the word organization.

We also want to express concern over the reference to FAR Part 9.5. **Appendix I, Qualification and Eligibility Information indicates that FAR Part 9.5 will be used as a guide in analyzing and resolving organizational COIs relating to an award. FAR 9.5 will also be used as a guide in analyzing and resolving organizational COIs relating to assistance agreements. A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be resolved.**

Our member institutions have established their policies in accordance with §200.112 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Most recently, the Council on Financial Assistance Reform (COFAR) has provided additional information through release of FAQ's to clarify that 20.112 is specifically meant to address how a federal awardee spends funds i.e., through procurements.

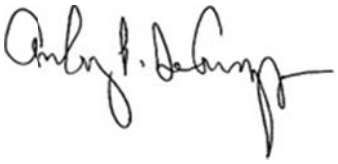
The Federal Acquisition Regulation establishes regulations and requirements that Federal agencies must follow when procuring goods and services. The Uniform Administrative Requirements, 2 CFR 200, by contrast, establishes requirements that must be followed by grantees when procuring goods and services needed to carry out a federal financial assistance award or subaward. COGR requests that the application instructions be clear to address the applicability that prime recipient and subrecipient institutions in receipt of federal funds follow their own conflict of interest policies when the award or resultant subaward is clearly programmatic in nature and not for the procurement of good and services. FAR Part 9.5 will be used as a guide for any contractor agreement for the procurement of goods and services necessary to carry out part of the Federal award.

In closing, pursuant to Executive Order 13563, Improving Regulation and Regulatory Review, and a number of committees, including the National Academies studying administrative burden, see: National Academies report, Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century," COGR's approach has been to work with agencies in a manner that effectively achieves the intended outcome of policies while producing the least amount of burden for both parties.

The intent of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards was to harmonize and 'unify' cost, administrative, and audit principles for federal grant recipients. COGR will continue to make efforts in the next year with organizations such as Federal Demonstration Partnership as well as our federal partners to work through these issues where agency implementations are different in an effort to harmonize and reduce administrative burden. We would welcome the opportunity to work with you. Please feel free to Jackie Bendall at jbendall@cogr.edu or myself at (202) 289-6655 should you have additional questions or concerns.

We look forward to hearing from you.

Sincerely,



Anthony P. DeCrappeo
President

General Submission Instructions

Broad Agency Announcement for Extramural Research (Program Specific)

Fiscal Years 2015/2016

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

Table of Contents

This General Submission Instructions document is one of two documents with instructions to prepare and submit a proposal/application for this funding opportunity. The second document, the Broad Agency Announcement, is available for downloading from Grants.gov.

I. HELPFUL INFORMATION

A. Tips for Success

 This symbol marks helpful hints throughout this document.

 This symbol refers to the Broad Agency Announcement for specific instructions.

B. Current Funding Opportunity Announcement

Proposals/applications to Defense Medical Research and Development Programs (DMRDP) – Program Specific Broad Agency Announcements (BAAs) for Extramural Research are being solicited by the US Army Medical Research Acquisition Activity (USAMRAA) for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. Through the US Army Medical Research and Materiel Command (USAMRMC), the Congressionally Directed Medical Research Programs (CDMRP) provides DMRDP execution management support for DHP core research program areas. Additional information may be found on the CDMRP's electronic Biomedical Research Application Portal (eBRAP) website at https://ebrap.org/ebrap/public/program.htm.

To view all funding opportunities currently offered by the CDMRP, perform a Grants.gov (http://www.grants.gov/) search using the Catalog of Federal Domestic Assistance (CFDA) Number 12.420. Additional information may be found on the CDMRP website at http://cdmrp.army.mil/funding/ and on eBRAP (https://ebrap.org/ebrap/public/program.htm). To receive email notifications when CDMRP funding opportunities are released, submit a request via email to help@eBRAP.org. Email notifications of funding opportunities are sent as a courtesy and should not be used as a sole source of notification; applicants should monitor Grants.gov for official postings of funding opportunities.

C. Receiving Emails from the CDMRP, eBRAP, and Grants.gov

To help ensure that all email correspondence is delivered correctly and is not treated as spam by email programs, keep your email address up to date in eBRAP and Grants.gov and place the following domains into your safelist: army.mil, us.army.mil, *.mail.mil, eBRAP.org, and grants.gov.

D. Agency Contacts

1. **CDMRP Help Desk:** Questions related to BAA content or submission requirements, as well as questions related to submission of pre-proposals/pre-applications 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. Eastern time. Response times may vary

depending upon the volume of inquiries. Be advised that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 301-682-5507

Email: help@eBRAP.org

2. **Grants.gov Contact Center:** Questions related to application submission through the 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 United States [U.S.] federal holidays).

Phone: 800-518-4726; (international) 1-606-545-5035

Email: support@grants.gov

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both: (1) pre-proposal/pre-application submission through eBRAP (https://eBRAP.org/); and (2) full proposal/application submission through Grants.gov (http://www.grants.gov/), with proposal/application status available on eBRAP.

A. Submission Dates and Times

All pre-proposal/pre-application and proposal/application components must be submitted by the deadlines identified in the BAA. Material submitted after the deadlines, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet any one of the deadlines will result in application rejection.

1. Pre-Proposal/Pre-Application Submission through eBRAP

All pre-proposals/pre-applications must be submitted through eBRAP (https://eBRAP.org/). A registration process through eBRAP must be completed before a pre-proposal/pre-application can be submitted.

2. Full Proposal/Application Submission through Grants.gov

A PI must be invited to submit a full proposal/application. An invited full proposal/application must be submitted electronically through Grants.gov (http://www.grants.gov). Proposals/ Applications will not be accepted by mail or in person.

To apply through Grants.gov, an organization must complete the Grants.gov registration process. Allow up to 4 weeks for the completion of the Grants.gov registration process. You are advised to register early.

Foreign organizations doing business outside of the U.S. are also required to complete the Grants.gov registration process, in addition to fulfilling supplementary requirements for doing business with the U.S. federal government.

If business is conducted with the federal government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management (SAM). Detailed information, automated tools, and checklists are available at http://www.grants.gov/web/grants/applicants/organization-registration.html.

The following steps are required as part of the Grants.gov registration process:

a. DUNS Number

The applicant organization and all subrecipient/subawardee organizations must have a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet. If an organization does not have a DUNS number, an authorized business official of the organization can request one by calling 866-705-5711 or by registering online (http://fedgov.dnb.com/webform/displayHomePage.do). Organizations located outside of the U.S. can request and register for a DUNS number on line via web registration (http://fedgov.dnb.com/webform/displayHomePage.do). Web registration can take 1-2 business days.

b. SAM Registry

The applicant organization must be registered as an Entity with the SAM (https://www.sam.gov) and receive confirmation of an "Active" status before submitting an application through Grants.gov. The SAM validates organization information and electronically shares the secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an Electronic Business POC, and a Government Business POC during the SAM registration process. ***Entity registrations in SAM have an annual expiration. Verify the status of your organization's Entity registration in SAM well in advance of the application submission deadline.*** An organization can register in SAM online at https://www.sam.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1 to 3 days. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the U.S. Internal Revenue Service. If you have the necessary information, online SAM registration will take about 1 hour to input, depending upon the size and complexity of your organization. Allow 3 to 4 weeks to complete the entire SAM registration process. ***Additional information and step-by-step registration directions are detailed in the SAM User Guide and other General Services Administration (GSA) training materials in the Help area at https://www.sam.gov.***

Proposals/Applications will be rejected by Grants.gov if (1) the organization's Entity registration in SAM is not active, and (2) if during the registration process, the organization did not answer "Yes" when asked, "Do you want to be eligible for grants and other federal assistance?"

c. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE Code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration goes through the validation process. Foreign registrants in SAM must be assigned a NATO CAGE Code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the company is located or by connecting to Form AC135 (http://www.xmarks.com/site/www.dlis.dla.mil/Forms/Form_AC135.asp). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

d. Authorized Organizational Representative (AOR)

Each organization must have an AOR who is registered with Grants.gov. Individual Principal Investigators do not register with Grants.gov; the Authorized Organizational Representative (AOR) is required to register. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before submitting an application, an organizational representative must register to submit on behalf of the organization at Grants.gov (http://apply07.grants.gov/apply/OrcRegister).

An AOR must first register with the Grants.gov credential provider at http://apply07.grants.gov/apply/OrcRegister to obtain a username and password. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Biz POC for assignment of user privileges. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

At the time of application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the application is current, accurate, and complete.

On occasion, the CDMRP may update or change the proposal/application package (hereinafter, application package) in Grants.gov. The applicant must use the latest version of the Grants.gov application package; proposals/applications submitted with a different version of the application package will not be accepted by Grants.gov. ***Sign up in Grants.gov (http://www.grants.gov/) for "Send me change notification emails" by following the link on the Synopsis page for the BAA or by responding to the prompt provided by Grants.gov when first downloading the application package***.

Submission of proposals/applications from federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. Refer to Section II.C.5., Research & Related Budget, for additional information.

B. Content and Form of Pre-Proposal/Pre-Application Submission

For specific instructions regarding content of the pre-proposal/pre-application submission components, refer to the BAA.

All pre-proposal/pre-application components must be submitted through eBRAP (https://eBRAP.org/). Remember to press the "Submit" button to finalize the pre-proposal/pre-application.

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs:

Tab 1 – Application Information: Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

Tab 2 – Application Contacts: Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted. **If the Business Official cannot be found in eBRAP, an invitation must be sent to him/her to register in eBRAP.** eBRAP does not require approval of the pre-proposal/pre-application by the PI's organization.

Tab 3 – Collaborators and Key Personnel: Enter the name, organization, and role of all collaborators and key personnel associated with the application.

The CDMRP does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Applicants should assign the role of each participant in accordance with the participant's respective involvement in the project.

Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in any pre-proposal/pre-application and full proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. Refer to the specific BAA for additional information.

If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), those Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors in proposals/applications for funding. For FY15/16, the peer review contractor is SRA International, Inc. The programmatic review contractor is Leidos, Inc. Proposals/Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to resolve COIs are provided and deemed appropriate by the government. Questions

related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to Appendix 1 for additional information.

Tab 4 – Conflicts of Interest: To avoid COIs during the screening and review processes, list all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

Tab 5 – Pre-Application Files: Upload all documents as specified in the BAA. Documents should conform to the formatting guidelines outlined in Appendix 2.

- ***Data Fields (if applicable):*** eBRAP will truncate characters exceeding the limit specified for each data field as specified in the BAA.
- ***Files (if applicable):*** eBRAP will not allow a document to be uploaded in the Required Files tab if the number of pages exceeds the limits specified in the BAA.

Tab 6 – Submit Pre-Proposal/Pre-Application: Enter password in the space provided next to "Enter Your Password Here" and press the "Submit" button. Press the "Confirm Submission" button to complete the pre-proposal/pre-application submission.

Following completion of pre-proposal/pre-application submission, the status in eBRAP will change from "DRAFT" to "SUBMITTED" and a confirmation email will be sent to the PI and named Business Official. ***An applicant with a pre-application in draft status after the pre-application submission deadline is ineligible to submit an application.***

C. Content and Form of Proposal/Application Submission

Each proposal/application submission must include the completed Grants.gov application package of forms associated with the BAA in Grants.gov (http://www.grants.gov/).

A compatible version of Adobe Reader must be used to view, complete, and submit the Grants.gov application package. ***Grants.gov will reject an application package that is opened at any time by an individual with an incompatible version of Adobe Reader.*** It is the applicant's responsibility to verify his/her Adobe Reader's compatibility with Grants.gov: http://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-compatibility.html. A no-cost compatible version of Adobe Reader can be downloaded at http://get.adobe.com/reader/otherversions/. Rejected proposals/applications must be resubmitted using a new application package and a supported version of Adobe Reader.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Verification of Grants.gov proposal/application in eBRAP:

The ability to view and modify the Grants.gov application in eBRAP is contingent upon an organization, its Business Officials, and its PIs registering and being affiliated in eBRAP.

eBRAP registration instructions are available in the user guide at https://ebrap.org/eBRAP/public/UserGuide.pdf.

For invited full proposals/applications, following eBRAP retrieval and validation of the Grants.gov application, eBRAP will notify the organizational representatives and PI to log into eBRAP to review, modify, and verify the Grants.gov proposal/application submission. eBRAP will validate retrieved files against the BAA requirements and discrepancies will be noted in both the email and in the Full Application Files tab. eBRAP does not confirm the accuracy or completeness of file content. ***It is the applicant's responsibility to review all proposal/application components.***

The PI will have a period of 5 days from the date of proposal/application submission to Grants.gov, i.e., ***the verification period***, to complete this process. Once the verification period has ended, the PI will not be able to modify proposal/application components. ***If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID.***

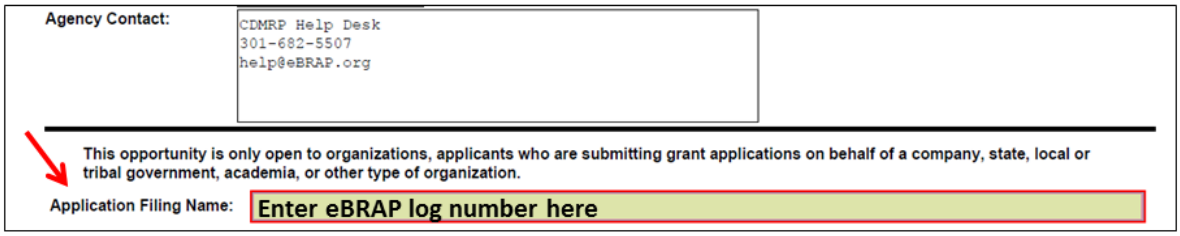
The proposal/application consists of the following components:

1. eBRAP Log Number

During the pre-proposal/pre-application process, each submission will be assigned a unique log number by eBRAP in the following format: BA15xxxx. The corresponding Grants.gov application package must be submitted using this unique eBRAP log number. Enter the eBRAP log number in one of two ways:

- **Manual Entry:** Fill in the **Application Filing Name** on the first screen of the Application Package (Figure 1) using only the **eBRAP log number** (e.g., BA15xxxx) assigned during the pre-proposal/pre-application process.
- **System-to-System Entry:** If a system-to-system interface with Grants.gov is being used, enter the eBRAP log number acquired during the pre-proposal/pre-application process into the **Submission Title** field.

Figure 1. Manual Entry of eBRAP Log Number in Grant Application Package



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

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in this application package. See below for clarification to general instructions:

- **Block 1 – Type of Submission.** For original submissions, select the "Application" box. For changes that must be made after the original submission, the complete package must be resubmitted with the "Changed/Corrected Application" box selected.
- **Block 2 – Date Submitted.** Enter the date the proposal/application is submitted.
    - **Applicant Identifier.** Enter the submitting organization's Control Number, if applicable. If there is no Organization Control Number, leave this field blank.
- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.
- **Block 4a. Federal Identifier Box.** This box will be populated by Grants.gov for an original application.
- **Block 4b. Agency Routing Identifier.** Not applicable.
- **Block 4c. Previous Grants.gov Tracking ID.** For changed/corrected proposals/applications, enter the Grants.gov tracking number (the federal Identifier Number assigned to the original proposal/application).
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. "Person to be contacted on matters involving this application" is the Business Official.
- **Block 6 – Employer Identification.** Enter the Employer Identification Number (EIN) or Tax Identification Number (TIN) as assigned by the Internal Revenue Service. If applying from an organization outside the U.S., enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select "New" for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-proposal/pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. The estimated start date should be no earlier than 4 months after the period of Programmatic Review as indicated on the title page of the BAA. The estimated end date should reflect the time needed to successfully complete the proposed project and not exceed the maximum period of performance allowed by the BAA. Actual start and end dates will be determined during negotiations if the proposal/application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the U.S., enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the proposal/application. If outside the U.S., select the appropriate country from the drop-down menu.

- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget and be consistent with the pre-proposal/pre-application budget.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option "b. NO, program is not covered by E.O.12372."
- **Block 17 – Complete Certification.** Select the "I agree" box to provide the required certifications and assurances**.**
- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL to disclose lobbying activities pursuant to Title 31 United States Code Section 1352 (31 USC 1352).
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is not an actual signature and is automatically completed upon submission of the electronic application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.

3. Attachments Form

Grants.gov does not validate for the presence of attachments on this Attachments Form. Each attachment to the Grants.gov proposal/application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted or for other guidance.

For specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form, refer to the BAA.

All documents that require signatures must be signed. Both electronic and hand signatures will be accepted. Any document that is signed by hand should be scanned at a low resolution such as 100-150 dots per inch**.**

The following must be included as attachments to this form:

Attachment 1: Project Narrative: Named "ProjectNarrative.pdf." The Project Narrative is the main body of the proposal/application. 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. There is no form for this information. A detailed description of the research to be undertaken should be submitted. This should include the areas described in the BAA**.**

Attachment 2: Supporting Documentation: Combine and attach as a **single PDF file named "Support.pdf."** Include only supporting documentation as indicated in the BAA. ***The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.***

All applications are provided fair and thorough reviews. Letters of support not requested in the BAA, such as those from members of Congress, do not impact proposal/application review or funding decisions.

For a list and descriptions of required supporting documents, refer to the BAA.

Attachment 3: Technical Abstract: Named "TechAbs.pdf." Abstracts of all funded research projects will be posted on the CDMRP website at http://cdmrp.army.mil. Do ***not*** include proprietary or confidential information. ***Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.***

Attachment 4: Lay Abstract: Named "LayAbs.pdf." Abstracts of all funded research projects will be posted on the CDMRP website at http://cdmrp.army.mil. Do ***not*** include proprietary or confidential information. ***Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.***

Attachment 5: Statement of Work (SOW): Named "SOW.pdf." The SOW outlines and establishes the PI's and an organization's performance expectations for which CDMRP may provide funding. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under Freedom of Information Act (FOIA).

A series of relatively short statements should be included describing the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award.

For specific instructions regarding the SOW content, refer to the BAA.

SOW format: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. ***The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding***

Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching. The Government reserves the right to request a revised SOW format and/or additional information.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the BAA (e.g., "Impact," "COI.pdf," "MFBudget.pdf," etc.).

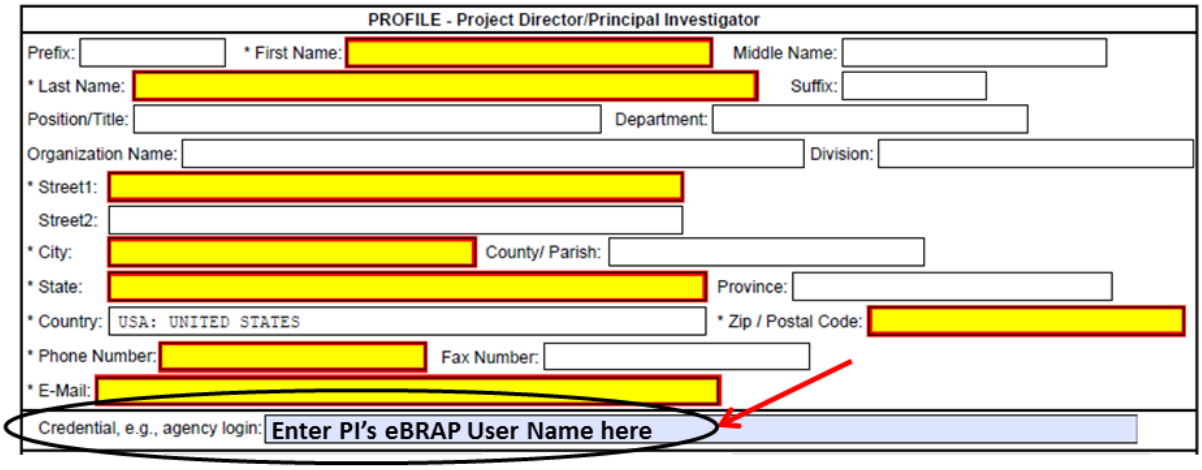
For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the BAA.

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

Include the requested information for each person who will contribute significantly to the proposed research project.

In the "PROFILE – Project Director/Principal Investigator" section, enter the PI's username provided by eBRAP into the data field labeled "Credential, e.g., agency login" (Figure 2).

Figure 2. PI's eBRAP User Name



Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the "Funding Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. Use of this document is optional. Each biographical sketch must be in PDF format prior to attachment.

a. PI Biographical Sketch: This file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the PI.

b. PI Previous/Current/Pending Support: This file must be titled "Support_LastName.pdf," where "LastName" is the last name of the PI.

For all previous (award period of performance ending within the past 5 years), current, and pending research support, include the title, time commitments,

supporting agency, name and address of the funding agency's procuring Contracting or Grants Officer, performance period, level of funding, brief description of the project's goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

c. Key Personnel Biographical Sketches: Each file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the respective individual.

d. Key Personnel Previous/Current/Pending Support: Each file must be titled "Support_LastName.pdf," where "LastName" is the last name of the respective individual. Refer to content requirements under "PI Previous/Current/Pending Support" listed above.

5. Research & Related Budget

An estimate of the total proposed research project costs, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget form. ***Include a sufficiently detailed budget and budget justification*** so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1. At the time of proposal/application submission to Grants.gov, the Authorized Organizational Representative is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

For limits on funding amounts, types of costs, and period of performance, refer to the BAA. Proposed costs that exceed the maximum allowed or of types not allowed may result in administrative withdrawal of the pre-proposal/pre-application or proposal/application.

For all federal agencies or organizations collaborating with federal agencies applying to an FY15/16 DMRDP BAA for Extramural Research, special restrictions apply to the budget as described on page 15.

Budget Regulations and Restrictions

Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the DoD's implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR[1] part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

[1] Code of Federal Regulations

- **Administrative and Cost Principles.** Proposers/Applicants will be required to comply with the following, as applicable:
    - 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the DoD interim implementation found at 2 CFR part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR part 200" (79 FR 76047, December 19, 2014). Terms and conditions of assistance agreement (grants and cooperative agreements) awards made after December 26, 2014 may reflect DoD's further implementation of 2 CFR part 200.
    - Provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant and Agreement Regulations," parts 26, 28, 34, and 1125.
    - Federal Acquisition Regulation (FAR) Part 31
    - Defense FAR Supplement Part 231
- **Award Funding/Maximum Obligation:**
    - **Contract Awards:** Reference contract funding regulations in FAR part 32.7 and DFARs part 232.7.
    - **Assistance Agreement Awards:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Pre-Award Costs:** Pre-award costs are allowable as follow:
    - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. A pre-contract cost agreement must be executed by the Contracting Officer prior to incurring any cost. The costs incurred must be allowable and allocable under the resultant contract. Payment will not be made until a contract is awarded. If the parties are unable to reach agreement on the award of the proposed contract, the Government shall be under no obligation to reimburse the contractor for any costs incurred.
    - **Assistance Agreement Awards:** An institution of higher education or non-profit organization may, at its own risk and without the federal government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award, if such costs (1) are necessary to conduct the project; and (2) would be allowable under the award, if awarded, without the government's prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the costs. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period. For-profit organizations must obtain the Grants Officer's approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award.

      The incurrence of pre-award costs imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is

made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. The Government expects the contractor/recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.

- **Cost of Preparing Proposals/Applications:** The cost of preparing proposals/ applications in response to a BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals/applications may be an allowable expense included in the indirect/facilities and administrative cost as specified in the organization's applicable cost principles and the FAR Part 31 and DFARs Part 231.
- **Currency:** All costs must be entered in U.S. dollars. Organizations performing research outside of the U.S. should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used.

Submit a detailed budget and justification that covers the entire period of performance (not just the first year). The Government reserves the right to request a revised budget and budget justification and/or additional information.

Budget Instructions: Complete the Research & Related Budget following the instructions below. Begin by entering the organizational DUNS number, Budget Type, Name of Organization, and anticipated start and end dates. ***Ensure that the DUNS number is entered accurately or Grants.gov will reject the proposal/application. Federal agencies applying as the applicant organization are required to have a DUNS number.***

For all federal agencies or organizations collaborating with Military Facilities applying to an FY15/16 DMRDP BAA, special restrictions apply to the budget and are described below.

For Federal Agencies: A proposal/application from a federal agency must include in the budget justification a **Federal Financial Plan (Plan).** The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

For Collaborating Military Facilities: A proposal/application from an organization that includes collaboration with a Military Facility must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Section II.C.8., Collaborating with DoD Military Facilities.

Section A: Senior/Key Person

1. **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the

applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under section F.3.

2. **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

3. **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. ***For most federal agencies, funding cannot be applied toward federal salaries; therefore, these salaries should not be included in the requested budget.***

4. **Calendar, Academic, and Summer Months:** For each senior/key person, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.

5. **Requested Salary:** Enter the amount of salary requested for this budget period.

6. **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the proposal/application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).

7. **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.

8. **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

1. **Number of Personnel:** For each project role category indicate the number of personnel for the proposed research project, including unpaid personnel.

2. **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.

3. **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.

4. **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most federal agencies, funding cannot be applied toward federal salaries; therefore, these salaries should not be included in the requested budget.***

5. **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the proposal/application is recommended for funding, the organization will be required to provide

documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).

6. **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description: Equipment is any article of non-expendable tangible property to be charged directly to the award and having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit (unless the applicant organization's policy has established a limit lower than $5,000). Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

1. Special test equipment to be fabricated for specific research purposes and its cost.
2. Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
3. Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for federal income tax purposes.

   In addition, requests for equipment must include a rationale for estimated costs.

Section D: Travel: Travel costs may include:

1. Costs to attend one or more scientific/technical meetings per year: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be well justified and is subject to approval.
2. Costs for travel associated with the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be well justified and is subject to approval.
3. Travel costs of military and DoD civilian employees that are approved for this project will be paid by the Government. No funds may be paid by the organization to any DoD civilian employee or military to cover such costs.
4. The PI may be required to participate in an In-Progress Review (IPR). The PI shall budget for, prepare for, and participate in an IPR, lasting not more than two days and including up to two overnight stays, for each year of the project's term, at the Contracting Officer's Representative's/Grants Officer's Representative's (COR/GOR) request. The invitation and format for the IPR will be provided by the COR/GOR at least (90) days prior to the meeting. The meetings will generally be held in the Fort Detrick, MD area but could occur elsewhere in the U.S.

Section E: Participant/Trainee Support Costs: Enter the funds requested for tuition/fees, health insurance, stipends, travel, subsistence, and other costs.

Section F: Other Direct Costs

1. **Materials and Supplies:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing $5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

2. **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

3. **Consultant Services:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

4. **ADP/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates. See Section F.9., "Other Expenses" for information regarding purchase of computers.

5. **Subaward/Consortium/Contractual Costs:** Include the total funds (direct and indirect costs) requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.

6. **For Military Facilities** collaborating in the performance of the project, a separate budget form and justification is required and submitted as an attachment. See Section II.C.8., Collaborating with DoD Military Facilities, for more information.

7. **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.

8. **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. Costs for the construction of facilities are not allowable.

9. **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule.

   Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project. If a computer/software purchase is requested, include the following in the budget justification:

   - Detailed explanation for why purchase of computer/software is required to complete the proposed research project.
   - Statement verifying that the requested computer/software is not currently available for use by the PI.
   - Statement assuring that the requested computer/software will be purchased in accordance with applicable cost principles.

   Include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs: Include the total direct costs (A-F).

Section H: Indirect Costs: The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a federal agency, indicate the source of the approval.

Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on- or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Provide documentation to support the indirect cost rate (e.g., the current DHHS, DCAA, or ONR Rate Agreement, other federally approved rate agreement, or other policy document) via eBRAP (https://eBRAP.org).

If a negotiated approved rate(s) does not exist, provide sufficient detail for a proposed rate (adhering to the applicable cost principles) in the budget justification. Organizations can also visit the DHHS (https://rates.psc.gov/fms/dca/negotiations.html), the Office of Naval Research (http://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx), and the Defense Contract Audit Agency (http://www.dcaa.mil/) for additional information on indirect rates.

Section I: Total Direct and Indirect Costs: Include total costs for the proposed research project.

Section J: Fee: Charging a fee or profit to an assistance agreement, either by the recipient/awardee or the subrecipient/subawardee, is prohibited.

Section K: Budget Justification: Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to section K of the Research & Related Budget.

Proposals/Applications from **federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

Organizations must provide sufficient detail and justification to enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

6. Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the "Next Site" button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

7. R & R Subaward Budget Attachment(s) Form (if applicable)

Complete a separate detailed Research & Related Budget (direct and indirect costs) including a budget justification for each subaward (subgrant or subcontract) in accordance with the instructions listed above. Title each individual subaward, "Research & Related Budget," with the name of the subawardee organization, and attach to the R & R Subaward Budget Attachment(s) Form.

A description of services or materials that are to be provided under the subaward is required. Organizations must provide sufficient detail and justification to enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

8. Collaborating with DoD Military Facilities

When a Military Facility will be a collaborator in performance of the project, complete a separate **"Collaborating DoD Military Facility Budget Form,"** including a budget justification, for each Military Facility.

A description of services or materials that are to be provided by the collaborating Military Facility is required. Applicant organizations must provide sufficient detail and justification to

enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

The contractor or recipient may provide resources to the Military Facility, such as personnel, supplies, or equipment, paid for/purchased using award funds. The resources to be provided should be identified in the proposal/application. These funds should be included in the applicant organization's budget and not included on the collaborating Military Facility's budget form.

If the Military Facility anticipates incurring costs, the Military Facility researcher must coordinate with his/her local Resource Management (RM) office (or equivalent) to prepare a sound budget and justification for the estimated costs. The Military Facility researcher should also coordinate with his/her technology transfer office, when applicable. Where there are no DoD-established reimbursement rates [e.g., institutional review board (IRB) fees, indirect cost rates, etc.], the Military Facility's RM office (or equivalent) must provide details of how the proposed rates were determined. The Military Facilities' direct and indirect costs to be supported when performing collaborative research with the contractor/recipient must meet the requirements of the DoD's Financial Management Regulation (FMR) 7000.14-R. Note that military and DoD civilian employee travel costs cannot be paid with award funds.

If possible, the USAMRMC's RM office will "direct fund" [via a Funding Authorization Document, Military Interdepartmental Purchase Request, or other authorized method] the collaborating Military Facility to support its costs to be incurred in performance of the Military Facility's portion of the research project awarded to the applicant organization. When "direct funded," these funds **will not** be included in the award amount to the contractor or recipient.

If extraordinary circumstances exist whereby the USAMRMC RM office is not able to "direct fund" the Military Facility, the contractor or recipient may provide award funds to the Military Facility. The Military Facility, in conjunction with the applicant organization, must provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility, the associated costs, when the activities will take place, why "direct funding" is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc. These funds would be included in the award amount to the contractor or recipient. Prior approval from the U.S. Army Medical Command, Principal Assistant Responsible for Contracting, is required under this funding method.

A cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) must be utilized for the contractor or recipient to provide award funds to the Military Facility. The CRADA (or other instrument) is not required at the time of proposal/application submission. A timeline for execution of the document will be established during negotiations.

APPENDIX 1

QUALIFICATION AND ELIGIBILITY INFORMATION

A. Recipient Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. To be qualified, a potential recipient must at least (1) have a satisfactory record of executing programs or activities under federal procurement or assistance or awards, if it is a prior recipient of such awards; (2) have a satisfactory record of integrity and business ethics; and (3) meet the qualifications and standards of the Federal Acquisition Regulations (FAR), Defense Federal Acquisition Regulations Supplement, and the Department of Defense Grant and Agreement Regulations.

The U.S. Army Medical Research Acquisition Activity (USAMRAA) utilizes the Exclusions within the Performance Information functional area of the System for Award Management (SAM), formerly the Excluded Parties List System (EPLS), to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/.

B. Eligibility Information

General eligibility for investigators, organizations, and agencies:

- Eligible Investigators: Includes all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization. ***Note: Awards are made to organizations only, not to individuals.*** Investigators must meet the specific BAA requirements.
- Eligible Organizations: The USAMRAA makes awards to national and international organizations. Eligible organizations include for-profit, non-profit, public, and private organizations, such as universities and colleges (including historically black colleges and universities, and minority institutions), hospitals, laboratories, and companies. Organizations must meet the specific BAA requirements.
- Government Agencies within the U.S.: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded intramural programs. Such agencies are required to explain how their applications do not overlap with their intramural programs.
- Intramural Investigators: Intramural investigators are eligible if the Funding Opportunity Announcement is not limited to submissions from extramural investigators only.

C. Conflict of Interest

All conflicts of interest (COIs) or potential COIs on the part of an organization or individual investigators that could bias the research project must be disclosed in the proposal/application submission, along with a plan to resolve them.

1. Contract Awards:

Organizational and Consultant Conflicts of Interest: Contracts must comply with the requirements found in FAR 9.5, Organizational and Consultant Conflicts of Interest. An organizational conflict of interest (COI) may result when factors create a potential or actual COI, or when the nature of the work to be performed creates a potential or actual COI on future acquisitions and some restrictions on future activities of the contractor may be required. FAR 9.5 will be used as a guide in analyzing and resolving organizational and consultant COIs relating to an award.

All COIs on the part of an organization or individual investigators that could bias the research results must be disclosed in the proposal, along with a plan to resolve them. An award may not be made if it is determined by the Contracting Officer that a COI cannot be avoided or mitigated.

2. Assistance Agreement Awards:

All awards must be free of any COIs that could bias the research results. You must disclose in the application all potential or actual COIs along with a plan to mitigate them. By signing the application, you are certifying, to the best of your knowledge and belief, that you have disclosed all potential or actual COIs.

All COIs must be resolved prior to the award of an assistance agreement. An award may not be made if it is determined by the Grants Officer that a COI cannot be avoided or mitigated.

Post-Employment Conflict of Interest – Contract Awards: There are certain post-employment restrictions on former Federal officers and employees as defined in Section 207 of Title 18 United States Code and Federal Acquisition Regulation (FAR), Part 3.104-3(c). If an organization believes a post-employment restriction or COI may exist, the situation should be discussed with the USAMRMC legal staff (301-619-6598) prior to expending time and effort in preparation of a proposal.

APPENDIX 2

FORMATTING GUIDELINES

All pre-proposal/pre-application and full proposal/application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point, not condensed.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project Narratives and pre-proposal/pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Inclusion of links to publications referenced in the proposal/application is encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the BAA (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB. ***If the file size for the entire application package will or may exceed 200 MB, applicants should contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that the file will be accepted or for other guidance.***

APPENDIX 3

ADMINISTRATIVE INFORMATION AND REQUIREMENTS

A. Disclosure of Proprietary Information

Do not include proprietary information in a pre-proposal/pre-application or abstract. Proprietary information should only be included in a full proposal/application if necessary for evaluation.

Proprietary information submitted in a proposal/application may be disclosed outside the government for the sole purpose of technical evaluation. Evaluators must agree that proprietary information in the proposal/application will be used for evaluation purposes only and will not be further disclosed or used.

All proposals/applications may be subject to public release under the Freedom of Information Act (FOIA) to the extent that they are incorporated into an award document; proposals/applications that are not selected for funding will not be subject to public release.

B. Marking of Proprietary Information

Conspicuously and legibly mark any proprietary information that is included in the proposal/application.

C. Award Notices

Awards are made to organizations, not to individual Principal Investigators (PIs). The DHP executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the government will be a matter of negotiation prior to award. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement.

1. **A procurement contract** is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government (31 USC 6303).

2. **An assistance agreement (grants or cooperative agreements)** is appropriate when the federal government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the U.S., instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the

award. DoD staff may become directly involved in performing the research, managing the effort, and/or reviewing and providing approval before work can proceed.

After email notification of proposal/application review results through the electronic Biomedical Research Application Portal (eBRAP), and if selected for funding, a representative from the U.S. Army Medical Research Acquisition Activity (USAMRAA) will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Contracting or Grants Officer may obligate the government to the expenditure of funds. No commitment on the part of the government should be inferred from discussions with any other individual. The award document signed by the Contracting or Grants Officer is the official authorizing documents.

D. Inquiry Review

If a proposal/application is not recommended for funding, the organization or PI may submit an inquiry within 30 business days after the date on which the funding status notification email for that proposal/application is sent. Inquiries submitted after 30 business days will not be considered. The inquiry must specifically address a **factual or procedural error** that is believed to have occurred during review of the proposal/application. Inquiries in response to funding recommendations should be submitted to the USAMRAA Contracting or Grants Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether a factual or procedural error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Contracting or Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

E. Information Service: Applicants may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone: 703-605-6000 (http://www.ntis.gov/) to obtain information about existing research to avoid duplication of scientific and engineering effort.

F. Freedom of Information Act Requests

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the FOIA (www.usdoj.gov/oip/index.html).

When a FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the applicant will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the applicant will be given notice of

USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

G. Information Release

A contractor or recipient of an award will be required to agree to the release of information pertaining to the research and development supported by the federal agency. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

The following are examples of statements that may be required. Specific required language will be included in each award.

1. All releases shall identify the award number and include a statement acknowledging the federal sponsoring agency. The release shall also contain a statement that the opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the Department of Defense (DoD). The requirement with specific language will be included in the award notice. Below is an example:

   "This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency, Research, Development, and Acquisition Directorate (or other sponsoring agency), through the (insert program name) under Award No. (W81XWH-15-1-XXXX). Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DoD."

2. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).

3. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules. (http://www.nih.gov)"

4. "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories. (http://www.cdc.gov/biosafety)"

Failure to comply may result in loss of funding.

H. Reporting Requirements for Awards

The government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the government will be described in each award and may include:

- Contractor Manpower Reporting (CMR)
    - CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing this data. A "nominal fee" is defined as a computation of an administrative assistant-equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.
    - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil.
    - Reporting input will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While input may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.
- Technical/Scientific:
    - Monthly, quarterly, and/or annual progress reports
    - Final progress report
    - Quad charts
    - Contractor manpower reporting

  Research progress reporting requirements and instructions can be found at https://mrmc-www.army.mil/index.cfm?pageid=mrmc_resources.rrpindex.

- Fiscal (SF 425 "Federal Financial Report") (assistance agreements only):
    - Quarterly and/or annual reports
    - Final report
- Regulatory:
    - Research with Human Subjects – For DoD awards that include funding to support research with human subjects, the USAMRMC's Human Research Protections Office (HRPO) requires submission of institutional continuing review reports and study event reports. Instructions are found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.
    - Research Involving Animals – For DoD awards that include funding to support animal studies, staff from the USAMRMC's Animal Care and Use Review Office (ACURO) will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

The government may request additional reports, which will be identified prior to award.

I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

J. Sharing of Data and Research Resources

It is the intent of the CDMRP that data and research resources generated by CDMRP -funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the CDMRP. This includes all data and research resources generated during the project's period of performance as annotated in the assistance agreement. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:

- **Unique Data**[2] are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.
- **Final Research Data**[3] are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
- **Research Resources**[4] include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

[2] Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique
[3] Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique
[4] Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf

Data and research resources generated from CDMRP-funded research should be made as widely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and third-party intellectual property.

By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with federal funds. The USAMRMC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.

- **Traumatic Brain Injury:** If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (https://fitbir.nih.gov).
- **Clinical Trials:** If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (http://www.clinicaltrials.gov).
- **Systems Biology:** If the project includes systems biology (SB) related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (http://sysbiocube-abcc.ncifcrf.gov).

K. Transfer of Award

Transfer of Contract: Transfer of a contract award to a new organization is not permitted.

Transfer of Assistance Agreement: Transfer of an assistance agreement to a new organization (e.g., if the PI relocates to another organization) will be considered on a case-by-case basis by the USAMRAA Grants Officer and will require the PI's original organization to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. The transfer of an award that includes a study site/clinical trial at its location will only be approved under unusual circumstances.

L. Change of Principal Investigator: A change of PI is not permitted except under extenuating circumstances that will be evaluated on a case-by-case basis by the Contracting or Grants Officer.

M. Property/Equipment

Contracts: Reference FAR Part 45 and DFARs Part 245.

Assistance Agreements: Unless otherwise specified in the award, the title to equipment or other tangible property purchased with government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the government. Title to equipment or other tangible property purchased by for-profit organizations will conditionally vest in the

organization subject to the requirements of the Department of Defense Grant and Agreement Regulations, Part 34.21. However, if the award is subsequently transferred to a new organization, the DoD reserves the right to require the transfer of equipment purchased with the award funds to the federal government or to an eligible third party.

N. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions and technical data, subject to meeting the reporting and patent filing requirements and retained rights to the government. The federal government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed. The FAR and DFAR govern the disposition of technical data rights, and generally the ownership of technical data is determined by the funding that governs it. For additional information, reference:

Contracts: FAR Part 27 and DFARs Part 227.

Assistance Agreements: DoDGAR 34.25 and 2 CFR 200.315-316.

O. J-1 Visa Waiver

An organization located outside of the U.S. may submit in response to the BAA. Each organization, located inside or outside of the U.S., is responsible for ensuring that the personnel associated with any proposal/application recommended for funding are able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the U.S.

Note: The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (http://www.state.gov/j/ct/list/c14151.htm).

Additional information on J-1 Visa Waivers can be located at the following Department of State website: http://www.travel.state.gov/content/visas/english/study-exchange/exchange.html.

APPENDIX 4

NATIONAL POLICY REQUIREMENTS

The following representations, certifications, and assurances listed in the Grants.gov application package of forms (SF424B) are applicable depending on the resultant award type**.** Any additional required representations, certifications, and assurances will be requested prior to award.

For regulatory requirements regarding the environment, and for use of animal and human subjects in research, refer to Appendix 5.

A. Contract Awards: Representations and Certifications: The applicant must complete the representations and certifications electronically via the System for Award Management (SAM) website accessed through https://www.acquisition.gov or https://www.sam.gov. By signing and submitting the proposal, the applicant certifies at that the representations and certifications currently posted electronically via SAM have been entered or updated within the last 12 months, are current, accurate, and complete, and applicable to the BAA.

B. Assistance Agreement Awards: National policy requirements applicable to the Department of Defense (DoD) awards are listed in Appendices A and B to Part 22 of the DoD Grant and Agreement Regulations (DoDGAR) (32 CFR Subtitle A, Chapter 1, Subchapter C) (http://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol1/xml/CFR-2011-title32-vol1-subtitleA-chapI-subchapC.xml).

1. Certification Regarding Lobbying Activities

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over $100,000. Submission of this certification is required by Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into an award over $100,000. Complete form Standard Form (SF) LLL, "Disclosure of Lobbying Activities," if applicable, and attach to Block 18 of the SF424 (R&R) form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

By signing a proposal/application, the applicant certifies, to the best of his or her knowledge and belief, that:

(1) No federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31 U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

2. Representations:

a. In accordance with DoD appropriations, organizations who are corporations are required to complete the representations below and submit with each proposal/application. The form for completion is posted in eBRAP (https://ebrap.org/eBRAP/public/Program.htm).

Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations under Any Federal Law (applicable to corporations only)

At the time of application submission, the applicant organization represents that it:

(1) Is _____ is not _____ a Corporation ("Corporation" means any entity, including any institution of higher education, other non-profit organization, or for-profit entity that has filed articles of incorporation) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

(2) Is _____ is not _____ a Corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

NOTE: If the applicant organization responds in the affirmative to either of the above representations, the organization is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the Government's interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

b. In accordance with DoD appropriations, the applicant's signature on the SF-424 affirms its agreement with the following representation:

Representation Regarding the Prohibition on Using Funds under Grants and Cooperative Agreements with Entities that Require Certain Internal Confidentiality Agreements

By submission of its proposal or application, the applicant represents that it does not require any of its employees, contractors, or subrecipients seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting those employees, contractors, or subrecipients from lawfully reporting that waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. Note that: (1) the basis for this representation is a prohibition in section 743 of the Financial Services and General Government Appropriations Act, 2015 (Division E of the Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113-235) and any successor provision of law on making funds available through grants and cooperative agreements to entities with certain internal confidentiality agreements or statements; and (2) section 743 states that it does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

3. **Requirements for Federal Funding Accountability and Transparency Act Implementation (2 CFR 170): Appendix A to Part 170**, incorporated herein by reference. The full text is available on http://www.usamraa.army.mil/.

4. **Financial Assistance Use of Universal Identifier and Central Contractor Registration (2 CFR 25): Appendix A to Part 25,** incorporated herein by reference. The full text is available on http://www.usamraa.army.mil/.

5. **Trafficking Victims Protection Act:**

   Trafficking in persons.

   a. Provisions applicable to a recipient that is a private entity.

      1. You, as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not:

         i. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;

         ii. Procure a commercial sex act during the period of time that award is in effect; or

         iii. Use forced labor in the performance of the award or subawards under the award.

      2. We, as the Federal awarding agency, may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity:

         i. Is determined to have violated a prohibition in paragraph a.1. of this award term; or

ii. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph a.1. of this award term through conduct that is either:

A. Associated with performance under this award; or

B. Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 CFR 1125.

b. Provision applicable to a recipient other than a private entity. We, as the Federal awarding agency, may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity:

1. Is determined to have violated an applicable prohibition in paragraph a.1. of this award term; or

2. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1. of this award term through conduct that is either:

i. Associated with performance under this award;

ii. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 CFR part 1125.

c. Provision applicable to any recipient.

1. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph a.1. of this award term.

2. Our right to terminate unilaterally that is described in paragraph a.2. or b. of this section:

i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 USC 7104(g)), and

ii. Is in addition to all other remedies for noncompliance that are available to us under this award.

3. You must include the requirements of paragraph a.1. of this award term in any subaward you make to a private entity.

d. Definitions. For the purpose of this award term:

1. "Employee" means either:

i. An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or

ii. Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.

2. "Forced labor" means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

3. "Private entity" means:

   i. Any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 CFR 175.25.

   ii. Includes:

      A. A non-profit organization, including any non-profit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 CFR 175.25(b).

      B. A for-profit organization.

4. "Severe forms of trafficking in persons," "commercial sex act," and "coercion" have the meanings given at section 103 of the TVPA, as amended (22 USC 7102).

C. Assurances for Assistance Agreements

The following list of Assurances, included herein by reference, will be included in full text as terms and conditions of each assistance agreement award, as applicable. The full text of the Assurances is available on http://www.usamraa.army.mil/.

- Nondiscrimination
- Campus Access for Military Recruiting and Reserve Officer Training Corps
- Research involving recombinant DNA molecules
- Radioactive materials
- Officials Not to Benefit
- Preference for U.S.-Flag Air Carriers
- Cargo Preference
- Environmental Standards
- Drug-Free Workplace
- Debarment and Suspension

APPENDIX 5

REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, DA PAM 385-10, 32 CFR 651 6 Sep 2012), provisions previously requested for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, select biological agents or toxins, select chemical agent(s), or pesticides outside of an established laboratory. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Surety, Safety, and Environment will identify any need for compliance review, and documents must be submitted upon request.

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the USAMRMC and involving human subjects, human anatomical substances, human data, human cadavers, and animals are conducted in accordance with federal, DoD, Army, USAMRMC, and international regulatory requirements.

Principal Investigators (PIs) and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until and unless regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, "Use of Animals in DoD Programs," as issued September 13, 2010, available at http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," as issued on November 8, 2011, and available at http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf.

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human data and/or specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI's institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_Animalappendix. ***Allow at least 2 to 3 months for regulatory review and approval processes for animal studies.***

For additional information, send questions via email to ACURO at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

D. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education, or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/assets/docs/orp/army-policy-for-use-of-human-cadavers_042012.pdf). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

E. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

In addition to local Institutional Review Board (IRB) review, investigators must submit all USAMRMC-funded research protocols involving human subjects and human anatomical substances for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (https://ebrap.org/eBRAP/public/Program.htm). This information is a guide only; it is not intended to be a source for human subject protection regulations. Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific laws and requirements governing research involving human subjects. These laws and directives may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already-approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the "Information for Investigators" found at https://mrmc.amedd.army.mil/assets/docs/orp/hrpo_information_for_investigators_050712.pdf. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

1. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.

2. **Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.

3. **Informed Consent Form:** The following must appear in the consent form:
   - A statement that the DoD is providing funding for the study.
   - A statement that representatives of the DoD are authorized to review research records.
   - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.

4. **Intent to Benefit:** The requirements of Title 10 United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an ***experimental subject*** in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of ***experimental subject*** as defined in the DoDI 3216.02 has a much narrower definition than ***human subject***. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at Usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

Research Monitor Requirement: ***For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.*** The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- overseeing study interventions and interactions;
- reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- shall have the responsibility for promptly reporting their observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

5. **Military Personnel Volunteers:** The following is important information for research projects proposing to include military personnel as volunteers.

   - **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with service-specific requirements.

     A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

     Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order service members to participate in a research study.

     For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

   - **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

   - **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

6. **Site Visits:** The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

   Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

7. **Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

D. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of "CDMRP-CDMRP Log Number" (e.g., CDMRP-BA16####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-CDMRP Log Number-A, B, C, etc." (e.g., CDMRP-BA16####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (http://clinicaltrials.gov/ct2/manage-recs/fdaaa) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

APPENDIX 6

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
BAA	Broad Agency Announcement
CAGE	Commercial and Government Entity
CCR	Central Contractor Registry
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ET	Eastern Time
F&A	Facilities and Administrative
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative
HIPAA	Health Information Portability and Accountability Act
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MHS	Military Health System
MPEG	Moving Picture Experts Group
NCAGE	NATO Commercial and Government Entity
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget

ORP	Office of Research Protections
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
SAM	System for Award Management
SOW	Statement of Work
TIFF	Tagged Image File Format
TIN	Tax Identification Number
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio

United States Army Medical Research and Materiel Command

DEPARTMENT OF DEFENSE

BROAD AGENCY ANNOUNCEMENT
for Extramural Medical Research

W81XWH-BAA-15-1

October 2014

Fort Detrick, Maryland

This Broad Agency Announcement document consists of two documents containing instructions on how to prepare and submit a proposal/application. The second document, the General Submission Instructions, is available for downloading from Grants.gov.

Table of Contents

NEW FOR FISCAL YEAR 2015

The Fiscal Year 2015 (FY15) U.S. Army Medical Research and Materiel Command's (USAMRMC) Broad Agency Announcement (BAA) for Extramural Medical Research contains several changes from previous USAMRMC BAAs. Read each section carefully. Note the following:

- The "Program Description" that describes the "Research Areas of Interest" has been updated.
- **Submission of a pre-proposal/pre-application is required.** After review, if the USAMRMC is interested in receiving a full proposal/application, the Principal Investigator (PI) will be invited to submit. A full proposal/application will not be accepted if the PI has not submitted a pre-proposal/pre-application and received an invitation to submit a full proposal/application.
- A PI and the organization's business official must register in the USAMRMC's new electronic Biomedical Research Application Portal (eBRAP) before submitting a pre-proposal/pre-application.
- All pre-proposals/pre-applications must be submitted through eBRAP. Invited full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.
- The Congressionally Directed Medical Research Program (CDMRP) office will be the execution management agent for this BAA; in general, this includes management of the new eBRAP system, receipt and processing of pre-proposals/pre-applications submitted through eBRAP, and retrieval and processing of full proposals/applications submitted to Grants.gov.
- Safety, surety, and environmental requirements have been revised.
- This BAA consists of two documents containing instructions on how to prepare and submit pre- and full proposals/applications. The second document, titled "General Submission Instructions," is available along with this BAA for downloading from Grants.gov.

NOTE: Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the Department of Defense's (DoD) implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR[1] part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

[1] Code of Federal Regulations

I. OVERVIEW OF THE FUNDING OPPORTUNITY

A. Administrative Overview

1. **Federal Agency Name: Department of Defense (U.S. Army Medical Research and Materiel Command)**
2. **Funding Opportunity Title: U.S. Army Medical Research and Materiel Command Broad Agency Announcement for Extramural Medical Research**
3. **Announcement Type: Broad Agency Announcement**
4. **Funding Opportunity Number: W81XWH-BAA-15-1**
5. **Catalog of Federal Domestic Assistance Number: 12.420**
6. **Key Dates:**

Release/Posted Date: October 1, 2014

Opening Date: October 1, 2014

Closing Date: September 30, 2015, 11:59 p.m. Eastern Time

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA). It is continuously open for a 12-month period, from October 1, 2014 through September 30, 2015, at 11:59 p.m. Eastern Time. This BAA must be read in conjunction with the application guidelines in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply). It must also be read in conjunction with the document titled "General Submission Instructions" available with this BAA in Grants.gov.

Pre-Proposals/Pre-Applications: To conserve both submitters' and federal government resources, organizations are ***required to submit preliminary proposals/applications (pre-proposals/pre-applications)*** so that the government can determine whether a proposed research idea meets the USAMRMC's mission and requirements described herein. Pre-proposal/pre-applications may be submitted at any time throughout the 12-month period noted above. All pre-proposals/pre-applications must be submitted through eBRAP (https://eBRAP.org/). A registration process through eBRAP (https://eBRAP.org) must be completed before a pre-proposal/pre-application can be submitted.

Full Proposals/Applications: To submit a full proposal/application, the PI must have received an invitation to submit from a Contracting or Grants Officer. An invited full proposal/application must be submitted electronically through Grants.gov (http://www.grants.gov/) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide. ***Proposals/Applications will not be accepted by mail or in person.***

Invited full proposals/applications can be submitted under the FY15 BAA through September 30, 2015. If an invited full proposal/application is not submitted by this date, it will have to be submitted under the FY16 BAA (to be posted October 1, 2015).

An invited full proposal/application submitted under this FY15 BAA will be considered for funding for a period of 24 months from the date of submission to Grants.gov.

A compatible version of Adobe is required for download from Grants.gov. For assistance downloading this or any Grants.gov package, contact Grants.gov Customer Support at http://www.grants.gov/contactus/contactus.jsp.

B. General Program Overview

The USAMRMC mission is to provide solutions to medical problems of importance to the American Service Member at home and abroad, as well as to the general public at large. The scope of this effort and the priorities attached to specific projects are influenced by changes in military and civilian medical science and technology, operational requirements, military threat assessments, and national defense strategies. The extramural research and development programs play a vital role in the fulfillment of the objectives established by the USAMRMC. General information on USAMRMC can be obtained at https://mrmc.detrick.army.mil/.

This BAA is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. In accordance with FAR 6.102, projects funded under this BAA must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

The selection process is highly competitive and the quantity of meaningful submissions (both pre-proposals/pre-applications and full proposals/applications) typically received exceed the number of awards that available funding can support.

This BAA provides a general description of USAMRMC's research and development programs, including research areas of interest, evaluation and selection criteria, pre-proposal/pre-application and full proposal/application preparation instructions, and general administrative information. Specific submission information and additional administrative requirements can be found in the document titled "General Submission Instructions" available in Grants.gov along with this BAA.

The execution management agent for this BAA will be the Congressionally Directed Medical Research Programs (CDMRP) office. The CDMRP manages the eBRAP system and retrieval and processing of full proposal/application submissions from Grants.gov. Refer to Section IX, Agency Contacts, for additional information.

The USAMRMC's supporting acquisition office, the U.S. Army Medical Research Acquisition Activity (USAMRAA), will be the awarding and administering office for proposals/applications selected for funding, unless approval is obtained from the USAMRMC Principal Assistant Responsible for Contracting to allow another federal acquisition office to execute and administer an award.

II. PROGRAM DESCRIPTION

A. Research Areas of Interest

1. Military Infectious Diseases Research Program

The Military Infectious Diseases Research Program (MIDRP) focuses on vaccines, anti-parasitic drugs, deployable field clinical diagnostics (human and vector), prophylactics and novel therapeutics to treat multidrug-resistant organisms in combat wound infections, as well as vector control pertinent to naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. Diseases of principal interest to the MIDRP are malaria, dengue, diarrheal disease caused by bacteria and norovirus, and human immunodeficiency virus (HIV). The MIDRP also has smaller research programs focused on scrub typhus, adenovirus, and hemorrhagic fever viruses that are not on the Defense Threat Reduction Agency (DTRA) biothreat list. Proposals/applications involving viral and bacterial biowarfare threats, chemical threats, and cancer research cannot be supported by the MIDRP.

Research efforts are needed in novel technologies for the prevention, treatment, and detection of naturally occurring infectious diseases. Areas of interest include norovirus and other viral diarrhea, Q fever (*Coxiella burnetii*), Crimean-Congo hemorrhagic fever, protozoal diarrhea, Rickettsiosis, Chikungunya virus, and technologies that leverage current research efforts in malaria, dengue, bacterial diarrhea, and HIV.

The MIDRP is also interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

a. Research and Development toward Preventive Measures for Infectious Diseases

- **Vaccines:** The MIDRP supports studies to characterize infectious agents that can result in a vaccine product, identify mechanisms of pathogenesis and protective immune responses in support of vaccine development, develop candidate field sites in conjunction with evaluation of vaccine efficacy in humans, and evaluate methods of vaccine delivery.
- **Anti-Parasitic Drugs:** Studies applicable to the discovery, design, and development of drugs to prevent malarial infections (including drug synthesis, screening of compounds, characterization of mode of action, and mechanisms of drug resistance) are of interest to the MIDRP. Additional topics for possible support include investigations of parasitic metabolism, structural biology, genomics, proteomics, and metabolomics directed toward the identification of potential novel molecular targets for intervention.
- **Vector Control Products:** The MIDRP supports investigations focusing on arthropod vectors and vector-borne diseases (with primary emphasis on malaria, dengue and scrub typhus). Current studies target vector-pathogen-human interactions, vector control (including personal protective measures), and risk assessment (including identification and classification of vectors, improved surveillance techniques, and field worthy assays for detecting pathogens in vectors).

The MIDRP also supports research toward products to detect, prevent, treat, and manage combat wound infections. In addition, novel chemotypes (chemical classes/materials[2]) and/or biologics as potential prophylactics/treatments for combat wound infection and/or biofilm formation are of interest.

b. Research and Development of Therapeutic Measures for Infectious Diseases

For the MIDRP, therapeutic drug development (including studies to screen, synthesize, and develop therapeutic drugs for malaria and other military-relevant infectious agents) is secondary to prophylactic development (see above). However, proposals/applications dealing with novel drug delivery systems (i.e., sustained-release and methods of targeting drugs to reduce toxicity or delivery of drugs of clinical importance to the active sites) would be considered. In addition, MIDRP supports investigations focusing on development of novel medical countermeasures and innovative treatment approaches (e.g., chelators, antibody, phage, antimicrobial peptides, quorum-sensing inhibitors, and host immunoaugmentation, etc.) for multidrug-resistant organisms in combat wound infections and/or biofilm formation, maintenance, or propagation. Given the tepid interest of the pharmaceutical industry to develop and market vaccines for diseases in areas of low commercial gain, the MIDRP is also interested in proposals/applications and products toward finding treatment options for infectious diseases that are likely to lead to U.S. Food and Drug Administration-licensable, broadly active therapeutics against multiple endemic disease threats.

2. Combat Casualty Care Research Program

The Combat Casualty Care Research Program (CCCRP) provides integrated capabilities for far-forward medical care to reduce the mortality and morbidity associated with major combat-related trauma across the spectrum of combat casualty care including point of injury and pre- or out-of-hospital care, the spectrum of en-route care, and facilities-based treatment. A primary emphasis of the CCCRP is to identify and develop medical techniques and materiel[3] (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries. Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, the CCCRP places a premium on medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. Preferred medical techniques and materiel that can be used by combat medics must be easily transportable (i.e., small, lightweight, and durable in extreme environments and handling); devices must be easy to use, low maintenance, with self-contained power sources as necessary. Drugs and biologics, ideally, should not require refrigeration or other special handling. All materiel and techniques must be simple and rapid to employ. The CCCRP is interested in existing material for which concept and/or patient care efficacy have already been demonstrated, but require improvement to meet military constraints. The CCCRP is also interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

[2] Material is defined as the tangible substance that goes into the makeup of a physical object.
[3] Materiel is defined as equipment and supplies of a military force.

Research efforts are needed in principles and technologies to enhance self- and buddy-aid, also referred to as tactical care; techniques, methods, or materials to improve basic and advanced life support for severely injured persons; monitoring, sustainment, and management of severely injured casualties during episodes of delayed or protracted evacuation; and enhanced capability for triage of large numbers of casualties and staged treatment in the field.

The principal causes of death among Service members who die within the first hour of wounding are hemorrhage and traumatic brain injury (TBI). As a consequence, the following areas are of particular interest to the CCCRP:

a. ***Research and development of technologies to stop blood loss, resuscitate the casualty, and limit the immediate, short- and long-term deleterious consequences of severe hemorrhage:*** Included in this area of interest are diagnostics and therapeutics to predict, diagnose, prevent, and treat coagulopathy of trauma and noninvasive or minimally invasive sensors to detect and warn of impending vascular collapse and/or significant tissue damage due to perfusion deficits. Examples of specific products include local and systemic hemostatic agents or devices (exovascular or endovascular) for control of vascular disruption and subsequent compressible and non-compressible hemorrhage, treatments to sustain or enhance oxygen delivery and perfusion of vital tissues and organs, and equipment and procedures for effective fluid resuscitation and enhanced resuscitation fluids. Also of interest are the improved preservation, storage, transportability, and processing of red blood cells, platelets, and plasma and other blood or blood-like substitutes.

b. ***Research and development of technologies to diagnose and to limit the immediate, short- and long-term impairments that follow TBI and spinal cord injury:*** Included in this area of interest are non- or minimally invasive sensors or assays to rapidly diagnose the severity of brain and spinal cord injury within the battle area (or as close to it as possible), and drugs, biologics, or other agents to mitigate post-injury neural and immune cell overstimulation, inflammation, cell loss, and/or neurologic dysfunction.

Secondary damage to organs frequently occurs after severe trauma and resuscitation. The CCCRP is interested in materiel and/or devices that can reduce acute secondary organ damage such as ischemia/reperfusion injury, cell death, general organ failure, and secondary brain/spinal cord damage. Technologies to sustain or support single and multiple organ injury and failure are also of interest to the CCCRP. These objectives include methods to reduce cellular demand for oxygen and metabolic substrates and therapeutics to modulate the immune response to traumatic injury as well as single and multiple organ support or replacement technologies (extracorporeal). The utilities of these modalities during and the effects of longer distance en-route care on the critically injured casualty are also of interest. These include, but are not limited to, hypobaria, hypoxia, and physiological effects of vibration, shock, and G-forces.

The CCCRP supports additional aspects of casualty care. These include drugs, devices, and/or novel surgical techniques to decontaminate, debride, protect, and stabilize hard and soft tissue wounds to mitigate secondary tissue damage; orthopedic and maxillofacial trauma repair strategies; and the prevention and treatment of dental injury or disease in austere environments. The CCCRP is also interested in the development of non-invasive sensors; diagnostic and prognostic algorithms; data gathering or capture modalities; and processors to improve our capability for remote triage, monitoring, and management of casualties; as well as products to maintain casualties during prolonged evacuation.

The CCCRP also supports the conduct of military-relevant clinical research aimed at translating knowledge or materials from basic and preclinical trauma research into clinical practice. This includes, but is not limited to, single and multi-center clinical trials performed in the civilian setting to clarify the safety, efficacy, and optimal use of products stemming from the previously mentioned research areas.

The CCCRP supports the conduct of military-relevant, large data research projects including the use of large databases of common elements from trauma research projects (preclinical, translational, and clinical). Such studies should directly contribute to or effectively enable the data-driven conduct of combat casualty care. Examples include, but are not limited to, post-hoc analysis of data from completed trauma research projects, meta-analyses of a number of otherwise separate but completed studies, and the ability to harmonize data from planned or ongoing but otherwise separate research studies.

3. Military Operational Medicine Research Program

The Military Operational Medicine Research Program (MOMRP) conducts biomedical research to deliver products and solutions to the Service member that address health and fitness throughout the deployment cycle. The MOMRP is centered on cutting-edge scientific research and bringing science to the Service member on the battlefield in a relevant, timely manner. The MOMRP is divided into four research focus areas: Injury Prevention and Reduction, Psychological Health and Resilience, Physiological Health, and Environmental Health and Protection.

The mission of the MOMRP is to develop effective countermeasures against stressors and to maximize health, performance and fitness to protect the whole Service member head-to-toe, inside and out, and at home and on the battlefield. The MOMRP is interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

The MOMRP focus areas of research emphasis are described below:

a. Injury Prevention and Reduction: This area of research addresses the requirement to provide the biomedical basis for countermeasures that prevent and mitigate Service member injuries that occur in training and operational environments and decrease attrition, medical cost, and minimize personal impact to the Service member. Specifically, this includes the need to prevent vision and hearing loss along with other blast-related and training injuries; identify validated fitness for duty/return-to-duty (RTD) standards following neurosensory and musculoskeletal injury; develop biomedically valid injury criteria and performance standards for individual (helmet and body armor) and crew protection systems; develop injury risk criteria and tools for health hazard and Service member survivability assessors; and Service member monitoring/sensor with accompanying algorithms that predict the likelihood of neurosensory, musculoskeletal, and brain injury.

b. Psychological Health and Resilience: Psychological health topic areas of interest include post-traumatic stress disorder (PTSD), suicide prevention, resilience, substance abuse, and violence within the military. Additional psychological health areas of interest that are understudied in the military context include military-related grief, guilt, or loss issues; moral

injury and/or anger, rage or aggression issues; interdisciplinary and comprehensive prevention and life-skills training strategies to reduce negative psychological health trajectories; psychosocial/psychological health challenges unique to military families, women Service members, the Reserve and Guard, persons of non-traditional sexual orientation, and sexual assault victims. This research area focuses on the development and validation of effective evidence-based training and prevention interventions, screening and assessment strategies, and treatment and rehabilitation interventions that address the psychological health topic areas and concussion/mild TBI as well as overall brain and cognitive fitness. Research areas of particular interest that are often overlooked but relevant include foundational studies to generate and validate theories and elucidate underlying mechanisms of psychological disorders and treatment response; studies addressing co-morbidities (including, but not limited to, PTSD, concussion, alcohol and other drug abuse, sleep disturbance, and mood disorders); studies focused on enhancing translation, implementation and uptake of evidence-based strategies and treatments; research focused on establishing validated objective RTD standards following psychological injury; and research focused on systems-approaches to psychological health. Research to incorporate and evaluate leveraging of technology (e.g., telemedicine, remote monitoring, biosensors, advance immunologic testing, and health information technologies) for prevention, treatment, and care management and decision support, and patient empowerment and education is of interest. Also of interest are rigorous studies on integrative medicine and complementary and alternative medicine (CAM) approaches spanning mind/body, movement, natural products, non-Western medicine approaches and spiritual practices, along with validation studies of CAM therapies. This area also supports research to inform the development of strategies for the diagnosis, treatment, and mitigation of cognitive dysfunction associated with TBI and war-related psychological injuries. Research topics of particular interest include those directed at evaluating efficacy of cognitive training approaches to promote resilience and prevent/mitigate acute negative responses to psychological trauma and promote brain health; and the development of a systematically applied set of therapeutic services designed to reduce cognitive dysfunction and restore functions that can be restored and/or improve quality of life.

c. Physiological Health: This area of research develops biomedical countermeasures to sustain Service member health and operational effectiveness and informs military policy, training, and the development of materiel solutions to establish, sustain, optimize, and monitor Service member health, physiological resilience, cognitive, and physical abilities throughout the military lifecycle, including training, deployment, reset, and injury recovery cycles. This research aims to prevent or mitigate the negative effects of operational and training stressors on the performance and fitness of Service members, as well as safely enhance performance with evidence-based pharmacological and non-pharmacological personalized strategies based on a systems medicine approach. Studies include use of dietary supplements and nutritional and behavioral interventions to mitigate threats to operational health and performance. Research also aims to develop advanced biomedical modeling and networked physiological status monitoring capabilities, healthy sleep and fatigue management strategies, development of strategies that exploit individual differences in sleep loss resilience, and individualized resilience to various operational stressors. Basic, applied, and advanced research studies utilizing technologies and strategies to monitor and promote Service member and family health to support the Surgeon General's Performance Triad are of interest.

d. Environmental Health and Protection: This area of research includes assessment and sustainment of health, force readiness, and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health hazards. In addition, this research includes development of policy, training, planning/management tools, knowledge and materiel solutions, psychological status monitoring systems, interventions and reset solutions, to sustain Service member resilience, health, and operational effectiveness to environmental stressors. Additional research identifies biomarkers of exposure to environmental health hazards, cognitive and physical performance assessment tools for exposures to environmental hazards, and development of hand-held, fieldable devices for rapid identification of exposure effect biomarkers in bodily fluids in support of military operational requirements.

The MOMRP supports research toward solving critical problems facing the Army today and in the future. Service- and platform-specific issues are addressed through close coordination with Navy and Air Force counterparts to prevent duplication of effort.

4. Clinical and Rehabilitative Medicine Research Program

The Clinical and Rehabilitative Medicine Research Program (CRMRP) focuses on the innovations required to reset our wounded Service Members, both in terms of duty performance and quality of life. Innovations developed from CRMRP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for RTD or civilian life. The interest is in medical technologies (drugs, biologics, and devices) and treatment/rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care provided to our wounded Service members within the DoD health care system. Implementation of these technologies and strategies should improve the rate of RTD of Service members, the time to RTD, clinical outcome measures, and quality of life, as well as reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care. Development and validation of in vitro and in vivo assessment models that represent military-relevant conditions in wounded Service members are of interest to the CRMRP when they can be used to identify and describe in a predictable manner the safety and efficacy of novel technologies in patients. The CRMRP is interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

The CRMRP focuses its efforts on the following research areas: neuromusculoskeletal injury (including amputees), sensory systems (including hearing, balance, tinnitus, and vision), acute and chronic pain, and regenerative medicine. While research topics of highest priority interest are listed below for each of these areas, proposals/applications for topics that align within an overall research area will also be considered, except as specifically noted. TBI research proposals/applications will only be considered if the focus is related to one or more of the following: hearing, balance, tinnitus, vision, or pain related to TBI. Novel manufacturing technologies necessary to translate innovative therapies or devices into clinical development are a focus.

All projects should adhere to a core set of reporting standards for rigorous study design. The CRMRP strongly encourages award recipients to follow the Animal Research: Reporting *In*

Vivo Experiments (ARRIVE) guidelines (http://www.nc3rs.org.uk/page.asp?id=1357). While these standards are written for animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

The CRMRP focus areas of research emphasis are described below:

a. ***Neuromusculoskeletal Injury Rehabilitation:*** Research directed toward functional outcome assessments focusing on return-to-duty and/or community reintegration. Of particular interest are technologies and rehabilitative strategies that restore function after sustaining neuromusculoskeletal injuries. Topics of interest include, but are not limited to, amputation, limb salvage, spinal cord and column injuries, polytrauma, contractures, and injuries such as sprains and strains that represent a significant burden of injury. Additional areas of interest include therapies to restore tissue and function, amputee-specific technologies and strategies that address/assess fitness sustainment and residual limb health, the prevention and treatment of heterotopic ossification, and mechanistic approaches to optimizing function in rehabilitative techniques and technologies.

b. ***Vision Restoration and Rehabilitation:*** Research aimed at treating traumatic and war-related injuries (including blast and burn injuries) to ocular structures and the visual system. Research focused on the diagnosis, treatment, and mitigation of TBI-associated visual dysfunction. Additional areas of interest include studies supporting diagnostic capabilities and assessment strategies, restoration of the visual system (including regeneration and tissue repair following traumatic injury), and vision rehabilitation strategies (including but not limited to rehabilitation for multi-sensory dysfunctions, low vision and blindness, and oculomotor and binocular vision disorders).

c. ***Hearing Loss/Dysfunction, Balance Disorders and Tinnitus:*** Research to support the development of strategies and technologies (including but not limited to medical devices, pharmaceuticals, and regenerative medicine based approaches) to restore and/or rehabilitate patients with hearing loss, balance disorders, and/or tinnitus due to trauma (including TBI). Research focused on the etiology of injury including studies to support an understanding of the molecular, cellular, and physiological mechanisms underlying hearing loss, balance disorders, and tinnitus. Additional areas of interest include studies supporting the development and evaluation of objective diagnostics for hearing loss, balance disorders, and tinnitus and research identifying and addressing the biopsychosocial aspects of auditory and vestibular dysfunction (including but not limited to the impact of co-morbidities and polypharmacy).

d. ***Pain Management:*** Primary interest is in management of pain associated with traumatic or war-related injuries. The CRMRP's specific needs include development of alternatives to current opioid analgesics for severe pain management by the medic/corpsman on the battlefield/remote locations; development of strategies for management of chronic pain under the care of a clinician in non-deployed settings; identification of pain generators, development of strategies for acute pain management in deployed locations, including battlefield and resource-limited environments; development of strategies for identifying and addressing biopsychosocial aspects of pain; development of strategies for management of acute pain under the care of a clinician in non-deployed settings; development of strategies

for chronic pain management in deployed locations, including battlefield and resource-limited environments; and development of substance misuse and abuse assessments and treatments in pain management.

e. ***Regenerative Medicine and Composite Tissue Engineering:*** Regenerative medicine involves the use of innovative technologies such as scaffolds and tissue engineering, growth factors, and cell-based treatments to restore Service members who have suffered extremity injuries, craniomaxillofacial injuries, burn injuries, or genitourinary/lower abdomen injuries. Research topics of particular interest include those directed toward the use of regenerative medicine-based technologies to repair functional nerve deficits (other than central nervous system or spinal cord), repair/replace neuromuscular tissue units of the extremities or face including composite facial features (eyelids, lips, and nares), regenerate bone defects (weight bearing and alveolar), regenerate skin, address vascular repair/revascularization, regenerate cartilage/musculoskeletal connective tissues for the prevention of post-traumatic arthritis, muscle protection/regeneration, repair/replace composite tissue units composed of two or more of the above-mentioned tissues, vascularized tissue allotransplantation, immunomodulation and tolerization related to vascularized tissue allotransplantation and wound management and tissue preservation such as promotion of scarless wound healing (not to include infection control). Research topics of particular interest addressing genitourinary/lower abdomen injuries focus on pelvic reconstruction and urogenital reconstruction. Pelvic reconstruction efforts should focus on promoting technologies that address injury to the anus. Urogenital reconstruction efforts should focus on promoting technologies that address injury to genitalia (penile, scrotal, urethral tissues), perineal tissue, and bladder.

5. Medical Biological Defense Research Program

The Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) manages research directed toward medical biological defense. The DTRA JSTO-CBD has limited funding for proposals/applications submitted through the USAMRMC BAA. DTRA also seeks proposals/applications for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovation Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, visit the website at http://www.dtra.mil/Business.aspx.

The Medical Biological Defense Research Program (MBDRP) provides medical countermeasures for biological warfare agents. These countermeasures include specialized medical materiel or procedures designed to enhance protection. The priorities of the program are (a) prophylaxis or pretreatment to prevent any casualty; (b) identification and diagnosis of biological agents; and (c) treatment or supportive care regimens. The MBDRP is interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

Examples of some of the infectious agents of interest are those causing anthrax, plague, glanders; the Ebola, Marburg, Venezuelan, western and eastern equine encephalitis viruses; and poxvirus models of variola virus. Examples of toxins of interest include those from plants (Ricin) and bacteria (Staphylococcal enterotoxins, botulinum).

The following are the overarching research and development goals:

a. Viral, Toxin and Bacterial Studies

- Identification and characterization of organisms and toxins. Molecular antigenic analysis; development of diagnostic assays; studies on structure and function that are related to mechanism of action, binding, internalization and interaction with the immune system and neutralizing antibodies; investigation of pathogenesis and immunology that will allow decisions regarding the optimal approach to disease prevention and control. Specific long-term goals include development of physiological support methodologies, diagnostic tests, rational prevention and control strategies, and improvement of existing products.
- Vaccine development, with emphasis on protection from agents in aerosol exposure, molecular approaches for development of vaccines, measurement of relevant cellular and humoral protective immune responses, and expression or production of protective antigens using recombinant technology. Development of vaccines for specific toxins and disease agents involving the generation, selection and characterization of attenuated strains or inactivated purified antigen preparations, to include polyvalent vaccines that are more broadly effective. Safer means of passive immunization such as production of human monoclonal or modified antibodies that are despeciated are also of interest. Identification of surrogate markers of protection for the agents identified above and development of assays to assess such protection are needed.
- Development of improved methods for delivery of vaccines, including adjuvants, nucleic acid vaccines, methods for oral or nasal immunization with inactivated, live, and subunit antigens; sustained release formulations; and development of methods for delivery of antigens for specific induction of mucosal immunity and development of methods to enhance appropriate immune responses to include co-delivery of cytokines.
- Preparation of research quantities of highly purified and characterized toxins as well as studies on basic chemistry, mechanisms of action, metabolism, and excretion.

b. Drug Development: Development, synthesis, and testing of compounds that possess antiviral, antibacterial, immunomodulatory or antitoxin activities, with emphasis on compounds that provide broad, nonspecific protection against viruses, bacteria and toxins described above. Studies of their pharmacokinetics and other measurements relevant to more effective drug use are also of interest. Development of lead compound(s) that are potent, active-site inhibitors that may include combinatorial-derived organic molecules and/or rationally designed transition-state substrate analogs. Testing for potency is required. Approaches that will be considered include, but are not limited to, computational chemistry, combinatorial organic synthesis, high-throughput in vitro screening and X-ray analysis of ligand-toxin co-crystals.

Research areas of interest include:

- Discovery of novel or unique biochemical elements or compounds with antiviral, antibacterial, or antitoxin activity against biological organisms.
- Development of testing models for evaluation of compounds effective against toxins of several classes, including pre- and post-synaptic toxins, membrane-damaging toxins, and toxins that inhibit protein synthesis and others.

- Mechanism of action studies of immunomodulators, including characterization of effector cells (lymphocytes, macrophages) effector mechanisms, ancillary effects on other cells of the immune system and production and characterization of cytokines released as a consequence of immunomodulation.

c. Identification and Diagnosis: The investigation and evaluation of sensitive and specific methods of identifying and diagnosing both antigens and antibodies of viruses, bacteria, and rickettsia in biological materials. Development of sensitive and specific immunologic, chemical, or biological assays for the rapid (within minutes) and reliable (1) diagnoses of acute diseases due to agents of potential biological threat and (2) identification of toxins or their metabolites in biological samples. Assay may include antigen, antibody or metabolite detection or the use of nucleic acid probes or synthetic antigens. In addition, there is interest in the development of rapid identification and diagnostic methods for the assay of toxins, metabolites and analogs in clinical specimens.

d. Biosurveillance (BSV): The process of gathering, integrating, analyzing and communicating a range of information that relates to health threats for people, animals, and plants to help inform decisions and provide for increased global health security. The Joint Biosurveillance Common Framework (JBCF) will be the first materiel solution and provides a single enterprise environment that supports collaboration, data sharing and coordination between multiple BSV stakeholders. The JBCF and future BSV applications, tools, and devices will provide a conduit between the medical, physical, and operational communities. This topic includes:

- Algorithms for rapid identification of baseline deviation; novel/unknown pathogens, naturally occurring versus intentional release.
- Models to predict the likelihood of an outbreak, forecast the associated epidemic curves and impacts of interventions, and update forecast based on field (and simulated) data.
- Applications to engage citizens via social media, crowd sourcing, gaming, etc.

In addition, two specific topics currently of interest are:

- Next-generation analytic capabilities for BSV: The objective is to develop next-generation methodologies to enhance analytic capabilities in the detect-identify-respond timeline for a bioevent. Research should be exploratory, with low technology readiness level, and should address long-term challenges in threat surveillance. Efforts should significantly contribute to the current body of knowledge and lead to new concepts for technology application that may have impact on future BSV analytic capabilities.
- Biosurveillance Ecosystem (BSVE) Analytics 2.0: The objective is to ensure state-of-the-art technologies are made rapidly accessible through the BSVE. This topic seeks to develop analytic applications to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of disease events. Metrics shall be devised such that successful utilization of these analytic tools will result in a measureable impact on the bioevent timeline. Efforts in this area should result in flexible, extensible, and sustainable analytics and models that are designed to plug into the BSVE as a la carte services rather than as standalone capabilities.

6. Medical Chemical Defense Research Program

The DTRA JSTO-CBD manages research directed toward medical chemical defense. The DTRA JSTO-CBD has limited funding for proposals/applications submitted through the USAMRMC BAA. DTRA also seeks proposals/applications for its requirements through the Federal Business Opportunities (FedBizOpps) and the DoD Small Business Innovation Research (SBIR) Program solicitations. For information regarding DTRA business opportunities, visit its website at http://www.dtra.mil/Business.aspx.

The Medical Chemical Defense Research Program (MCDRP) seeks to preserve combat effectiveness by timely provision of medical countermeasures in response to Joint Service chemical warfare defense requirements. The fundamental orientation of the program is to protect U.S. forces from the effects of chemical warfare agents by developing protective, pretreatment, and prophylactic products, providing products usable by the individual Service Member for immediate treatment of chemical warfare agent exposures, developing antidotes/therapeutics to chemical warfare agents, defining care procedures for chemical warfare agent casualties, and advancing management of these casualties. The medical countermeasures are intended to preserve and sustain the Service members' combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield. The MCDRP is interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

The broad goals of this program are described below:

a. Maintain the technologic capability to meet present requirements and counter future chemical warfare agent threats: The program will maintain the scientific base and technological capability to develop timely medical countermeasures for both current and future chemical warfare agent threats. Research funded by this program will be used to identify concepts and candidate medical countermeasures for use by the individual Service member or by medical personnel. Basic and applied research are both supported and may address topics as diverse as determining sites/mechanisms of action and effects of exposure to chemical warfare agents with emphasis on exploitation of neuroscience technology, and respiratory, ocular, and dermal pathophysiology; identifying sites and biochemical mechanisms of action of medical countermeasures; exploiting molecular biological and biotechnological approaches for development of new approaches for medical countermeasures to chemical warfare agents; and exploiting molecular modeling and quantitative structure-activity relationships in support of drug discovery and design.

b. Provide medical countermeasures for the individual Service member to maintain combat effectiveness and prevent or reduce injury from chemical warfare agents: This goal encompasses research supporting development of new concepts for prophylaxes, pretreatments, antidotes, and therapeutic countermeasures; development of skin protectants and decontaminants; identification of factors which influence safety and efficacy of candidate medical countermeasures; and development and maintenance of preformulation, formulation, and radiolabeling capabilities.

c. Provide medical management of chemical casualties to enhance survival and expedite the RTD of chemical warfare agent casualties through definitive therapies and life support technologies: This goal includes developing concepts and therapeutic regimens and procedures for the management of chemical warfare agent casualties; developing diagnostic and prognostic indicators for chemical warfare agent casualties; and developing life-support equipment for definitive care of chemical warfare agent casualties.

Recent changes in the security situation facing the U.S. have not materially reduced the threat that chemical weapons present to American forces in the field. Many Third World countries and terrorist groups have the capability of producing and delivering chemical warfare agents, thus posing a substantial and serious threat to the armed forces of the U.S.

Classical chemical agent threat categories include vesicant or blister agents (e.g., sulfur mustard), blood agents (e.g., cyanide), respiratory agents (e.g., phosgene), and nerve agents (e.g., GA or Tabun, GB or Sarin, GD or Soman, and VX).

Examples of pertinent research topics and areas currently of interest include:

- Characterizing the mechanisms of vesicant agent pathophysiology to identify medical countermeasures against vesicant agents.
- Developing innovative models of the pathophysiology of vesicant agent injury.
- Identifying and/or evaluating innovative candidate medical countermeasures against vesicant agents.
- Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to vesicant agent casualties.
- Characterizing the ocular lesions associated with vesicant agent exposures; developing treatments to ameliorate these injuries.
- Characterizing the mechanisms of nerve agent-induced seizures and resulting pathophysiology to identify medical countermeasures against nerve agent-induced seizures.
- Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against nerve agent-induced seizures.
- Developing innovative models of the pathophysiology of nerve agent induced seizures.
- Developing catalytic and/or stoichiometric chemical warfare agent scavengers from biological molecules (e.g., antibodies and enzymes) that provide protection against nerve agent incapacitation and lethality for extended periods following their administration.
- Developing innovative models for evaluation of chemical warfare agent scavengers.
- Identifying, expressing, synthesizing, and/or evaluating biotechnologically derived or pharmaceutically based scavengers as candidate medical countermeasures against chemical warfare agents.

- Developing and evaluating custom-synthesized pharmaceuticals based on a detailed understanding of the pathophysiology and mechanisms of action of the chemical warfare agent structure and the function of the intended target molecule.
- Developing catalytic and/or stoichiometric additives for use in skin protectants, or decontaminants, to protect against chemical warfare agents, especially vesicant and nerve agents.
- Developing innovative models for evaluation of catalytic and/or stoichiometric additives in skin protectants or decontaminants.
- Developing candidate formulations for skin protectants or decontaminants containing catalytic and/or stoichiometric additives and evaluating these formulations against chemical warfare agents.
- Characterizing the pathophysiology and natural progression of chemical warfare agent-induced damage to human tissues.
- Developing and validating innovative techniques for rapid and accurate analysis of human tissues and body fluids for detection of chemical warfare agent exposures.
- Characterizing the effects of long-term or chronic exposures to chemical warfare agents and/or medical countermeasures to these agents.
- Identifying, exploring, and developing innovative clinical diagnostic, prognostic and management approaches to nerve agent casualties.
- Developing and validating field usable procedures for diagnosis, prognosis, and treatment of chemical warfare agent casualties under both field and laboratory conditions.

7. Medical Simulation and Information Sciences Research Program

The mission of the Medical Simulation and Information Sciences Research Program (MSIS) is to explore the implications of models and technology for medical education and for the provision, management and support of health services in the military. The MSIS research program plans, coordinates, and oversees a responsive world-class, tri-service science and technology program focused on two areas of research. One area is focused on improving military medical training through medical modeling, simulation, educational gaming, assessment systems, and objective training metrics. The second area is focused on improving the use and sharing of health-related data for better strategic planning, process development, and software applications. It is organized into two portfolios, one for each of the two focus areas. Each portfolio is further organized into sub-focus areas as described below:

a. The Medical Modeling Simulation and Training Technologies Portfolio

- **Combat Casualty Training Initiative:** This initiative strives to advance pre-hospital combat casualty training with an emphasis on the combat first responder. Research in this area will examine the efficacy of modern simulation system technology versus current models as well as validation of system and training metrics/evaluation outcomes. Improvement of tissue fidelity, whether as it applies to mannequins or virtual reality, and accurate and appropriate tissue response to health care provider actions is another area of interest. The effort includes research and develops training assets for continual high state

of readiness and provides stress training prior to deployment to reduce/mitigate (inoculate) effects of anticipated stressors. Goals include:

- Optimization of critical lifesaving skills and procedures through training and educational simulation systems.
- Improved assessment systems of user's cognition, psychomotor skills, and affective behavior before, during, and after (retention) training.
- Emphasizing approaches toward "anytime readiness" in a near-future era of reduced deployment.
- Building psychological resilience into pre-deployment training.
- Significant improvements in material properties representing tissue as well as models that represent tissues in virtual reality.

- **Medical Practice Initiative:** This initiative focuses on the maintenance of military and medical skills over a medical provider's health care career. Research efforts are aligned with maximizing health care professionals' training and investigating degradation of existing medical cognitive and psychomotor skills. The initiative seeks to research improved intelligent automated assessment systems that will assist in directing and catering the type of training courses an individual needs as well as systems that connect medical training to real-world patient outcomes. The initiative will lead to further research and development in team-based cooperative training methods, patient transfer points and efforts related to evidence-based clinical skills with clear, definitive outcomes. Goals include:
  - Leveraging and creating training technology advances to keep U.S. military medicine on top.
  - Understanding acquisition of skills to achieve competency and proficiency and how to best maintain them.
  - Pioneering automated adaptive learning to tailor training to health care providers' needs.
  - Leading the way to a sustainable medical education lifecycle.
- **Health-Focused Initiative:** This initiative seeks to develop and test self-care technologies for patients use, whenever and wherever they choose to manage personal health and wellness. The Health-Focused Initiative is aimed at promoting patient engagement and resilience; this research will deliver technologies that improve the human-machine interface and bridge the gap between patients and clinicians. The focus is on advanced medical technologies research targeting the management of acute and chronic health challenges and technologies that encourage health promoting behaviors at home and in theater. Goals include:
  - Researching innovative learning and behavioral concepts that incorporate technologies to maximize compliance regardless if physical, medical, and/or psychological (behavioral) rehabilitation/recovery.

- Researching and applying social media and large database mining information along with effective and efficient learning theories to educate both individual and/or group with processing and decision making during acute, emergent, and catastrophic events.
- Emphasizing innovative learning and behavior concepts to educate individuals on healthy choices to potentially prevent medical conditions and encourages health promoting behaviors at home and in theater.

- **Tools for Medical Education:** This initiative assists in developing and testing trans-disciplinary open-source/open-licensed development toolkits and models that are accessible to the community at large, allowing developers to focus on content generation rather than on developing basic technology. This reduces content development costs and encourages a more diverse authorship community. Widely accepted standardization will enable instructors to greatly increase the available training opportunities at reduced cost. The intent is to shift the focus from developing basic medical training technology to generating evidence-based training content in order to improve patient safety, maximize system and organization-level return on investment, increase available training opportunities, and minimize training. Goals include:
  - Ensuring that advanced medical simulation capabilities are ubiquitous.
  - Researching effective, efficient, elegant, accurate, appropriate, and robust medical models (anatomical, physiological, and/or behaviorally) for next-generation mannequin prototyping and virtual reality/immersive reality models.
  - Democratizing access to advanced medical simulator technology so that it can be used by large and small innovators alike.
  - Saving money by eliminating wasteful and redundant research and development.

b. The Health Informatics and Health Information Technology Portfolio

- **Theater/Operational Health Services and Support:** Research in Theater/Operational Health Services and Support provides services to the armed forces to promote, improve, conserve, and restore the mental or physical well-being of personnel through improved information management and the use of emerging technologies in the following categories:
  - Medical Command and Control: Enable commanders to more efficiently and effectively manage medical information and medical workflows.
  - Medical Logistics and Blood Management: Explore transformational technologies to improve core logistics systems, e.g., information systems, automatic identification technologies, medical materiel management to include blood, oxygen, or other materiel with special environmental handling requirements.
  - Health Information Capture, Documentation, and Transmission to Include Biomonitoring and Telehealth/Mobile Health: Improve the capturing of physiologic data and care documentation from Role 1 through Role 3 and the transmission of that data to support patient care and evacuation, improve technology platforms for better physiologic monitoring during evacuation including enhancements to predictive algorithms and enhanced biosensory monitoring and communicative capabilities to

support the delivery of remote care and consultation across theater and garrison environments. Research to determine and prototype optimal information technology capabilities to support the provision of telehealth/telebehavioral health within theater and between theater and Role 4 facilities to include provider-to-provider as well as provider-to-patient interactions. Research to examine technology integration and clinical/business process integration to reduce implementation barriers with regard to remote health monitoring.

- Surgical Analytics Strategy Tactical Tools: Research into business analytics, modeling and decision support, and tools to examine population health forecasting and readiness management in military surgery.
- Global Health/Support Operations: Improved technologies to provide assistance during natural or manmade disasters worldwide. Research to determine and prototype optimal Information technology capabilities to support global humanitarian assistance health care missions in response to natural or manmade disasters.

- **Health Operations Resourcing:** Research to improve financial and personnel management for better delivery of health care services.
  - Training Management: Explore technologies to streamline the access to and management of educational systems across the Military Health System (MHS).
  - Provision of Training: Conduct research to explore the use of health informatics or information technology (HIT) in the provision of training.
- **Health Services and Population Health:** Research into how health care providers and patients can better use health services and population health-related information and technologies to improve health:
  - Clinical Decision Support: Improve systems or applications that will better assist health professionals in making clinical decisions.
  - Provide Unified View: Provide a user view of information that is comprehensive of the patient record with the ability to exclude certain sensitive information for specific users when necessary (e.g., mental health record information).
  - Computational Biology and Advanced Analytics: Focus on the development and application of methods for analysis, interpretation, prediction, and modeling of biological data. The objective is to use mathematical tools to extract practical information from data produced by high-throughput biological techniques. For more information, refer to Section V.E.2, Attachment 6.
- **Health Enterprise Infrastructure:** Research to improve health enterprise infrastructure by improving information technology and communications infrastructure.
  - System Interoperability: Research into system interfaces that will ensure that products or systems work efficiently with other products or systems, present or future, without any unintended restrictions.
  - Information Interoperability: Research to move toward a common data format capable of exchanging data seamlessly within the MHS and with external organizations.

- Medical Device Interoperability: Improve the ability for medical devices to securely and reliably exchange information with other devices and with medical documentation and management systems.
- Reliable Patient/Beneficiary Identification: Research to ensure the unique identification of each patient to support safe and efficient patient/beneficiary care and management.
- Data Management: Research to provide real-time access to data from sources in multiple, disparate physical locations and aggregation as necessary to facilitate crawling, indexing, security, identity, authentication, authorization, and privacy. Research to support making Milestone D decisions on legacy systems to include research to explore the mandatory data requirements (including legal or regulatory mandates) related to these decisions and to prototype alternative technical approaches.
  - Research to define the optimal transition model that enables write-back to Armed Forces Health Longitudinal Application (AHLTA), Composite Health Care System (CHCS), and Essentris as necessary but allows easy access to and search of past medical records, is legal (nonrepudiation), and realistically accommodates projected growth from initial operational capability to full operational capability.
  - Research to define the optimal approach to transitioning necessary encounter/clinical notes from AHLTA along and map the concepts for use in the modernized system for clinical care and research.
  - Research to define the optimal set of any other capabilities/data necessary for transition to support clinical analytics, research, and archiving.
  - Research to aid in determining alternative strategies for transitioning current MHS registries and to evaluate alternatives approaches through prototyping where useful.
  - Research to prototype and develop proofs of concepts prior to implementing production capabilities related to large volume terminology mapping using extract, transform, and load approaches in the Big Data Ecosystem.
  - Research to explore the optimal approach to the ability to persist data that are acquired through the legacy health information exchange.

8. Radiation Health Effects Research Program

The Radiation Health Effects Research Program (RHERP) focuses on developing medical countermeasures for acute ionizing radiation injury. The program has interest in the following research focus areas: post-exposure mitigation of radiation injury; protection and prevention of injury from ionizing radiation exposure (prophylaxis); mechanism of radiation injury; and development of novel biodosimetry tools. The RHERP is interested in proposals/applications and products incorporating a systems biology approach. For more information, refer to Section V.E.2, Attachment 6.

9. Special Investment Areas/Innovation Funding

The USAMRMC is continually seeking new and innovative science that promises benefit to military health and medicine. Many efforts are now integrated into programs of record or current research areas of interest as noted in this BAA. The USAMRMC initiatives of interest include, but are not limited to, cross-cutting new science and technologies that may not have an apparent place elsewhere in this announcement, non-hypothesis driven research, development of enabling technologies, and new uses of current science that have not been considered in the past for a given application. A part of the investment process involves activist management that encourages Service Member-centered projects that can be eventually integrated into the current research area taxonomy.

Innovation Funds may be available to support proposals/applications that offer proof of concept, prototype development, and other activities that initiate or enhance potentially "game-changing" technologies and systems. Innovation funds generally range from $100,000 to $500,000 per project and are for a limited period of performance, generally 18 months or less. Innovation Funding requests may include out-years, but these must be expressed as options to the government. Proposals/applications must be written in such a way as to ensure a valuable deliverable after the first period of performance; multi-year longitudinal plans with incremental deliverables do not fit the Innovation Funds paradigm and should be submitted as a standard BAA submission, consistent with guidance elsewhere in this BAA.

Examples include approaches based upon convergence science principles and may address investment areas such as:

a. Medical Logistics: The objective is to research potentially transformational technologies to apply to core logistics systems, focusing on devices, practices, and business processes that will improve military medical logistics. Research priorities include information systems and the application of automatic identification technologies to the management of medical materiel. This will include supply chain management and asset management (inventory and lifecycle management), business processes, and technologies. Technologies to support improved delivery of critical medical supplies including blood, oxygen, intravenous fluids, biologics, and other medical materiel that has specific environmental handling requirements and limitations, as well as medical assemblages to the battlefield are of interest. Improvements in the storage of these commodities in the austere environment are also of interest.

Innovations that improve and support optical fabrication, hospital services, facilities, and biomedical management and repair will be considered. Special attention may be given to the extension of advanced and transformational technologies to support the operational/deployed force. Areas of special interest include cold chain management in extreme conditions and the safe destruction/ management of medical, biological, and pharmaceutical waste in austere environments. The ability to treat and potentially recycle/reuse waste water (both gray water and black water) that may contain medical (biological) and/or chemical (pharmaceutical) contaminants may be included in this area of special interest.

b. Biomonitoring Technologies: Research focus is on the development and integration of systems and/or platforms of technologies that will enable (remote and wireless) monitoring of a person's health to include assessing environmental factors in any setting including at home, in hospital, or in the field. This also includes development of algorithms and decision support tools.

c. Cross-Cutting Technologies in Neuroscience: Research in this area includes training, treatment, prevention, protection, assessment, and diagnosis, using a variety of methodologies, techniques, materials, and technologies. Efforts in this area may fall in the following categories: brain-machine interfaces, neurodegenerative conditions, and neuroimaging.

d. Medical Robotics and Intelligent Systems: Objectives target adapting, integrating, and/or developing intelligent systems, human computer interfaces, and robotic technologies for medical applications. These include, but are not limited to, capabilities for location, assessment, treatment, and rescue of battlefield casualties and development and integration of clinical robotic/intelligent system capabilities to improve patient medical outcomes. These technologies are also enablers for other scientific and technology domains such as advanced prosthetics and human performance, trauma, health information technology, simulation and training, medical logistics, and nanomedicine and biomaterials.

e. Nanomedicine and Biomaterials: The objective is to identify novel developments in materials science and biomaterials that can lead to new drugs and improved devices for diagnosing diseases and treatments. This includes nanotechnology and material fabrication with properties that mimic biological tissues.

B. Research and Development of Devices or Technologies

The USAMRMC may provide financial support for research and development related to medical devices or technologies. Such projects should be for scientific study and experimentation directed toward advancing the state of the art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution (see FAR 6.102). Additional information is required for such projects as indicated below:

- Discussion of the technical feasibility of the proposed project including background of the problem, theoretical model/approach, previous and current solutions, an awareness of similar projects previously undertaken, and knowledge of related activities.
- Discussion of the engineering/technical design to achieve the project goals demonstrating the feasibility of the proposed product development. Discussion of the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.
- Discussion of the background intellectual property relevant to the project.
- Discussion of the plans for translation, implementation, and/or commercialization for the device or technology.

III. AWARD INFORMATION

A. Funds Available and Anticipated Number of Awards

A specific amount of funding has NOT been set aside for this BAA, and the number of awards is indeterminate and contingent upon funding availability. Selection of research projects is a highly competitive process and is based on the evaluation of the proposal/application's technical merit, programmatic considerations, and the availability of funds. The quantity of meaningful submissions received (both pre-proposals/pre-applications and full proposals/applications) normally exceeds the number of awards that the available funding can support. Any funding that is received by the USAMRMC and is appropriate for a research area described within this BAA may be utilized to fund proposals/applications.

B. Award Amounts and Periods of Performance

There are no specified funding limitations identified for a proposal/application submitted under this BAA, except for the "Special Investment Areas/Innovation Funding" area of interest. Funding for those projects generally ranges from $100,000 - $500,000 per project. A budget should be commensurate with the nature and complexity of the proposed research. Researchers should submit budgets that include the entire period of performance of the research project. Budgets should include all direct and indirect costs, based on supportable, verifiable estimates. The budget for the full proposal/application should not differ significantly from the Pre-Proposal/Pre-Application Budget Summary Form provided in the pre-proposal/pre-application submission.

The total period of performance may be up to 5 years in length, except for the "Special Investment Areas/Innovation Funding" area of interest. Periods of performance for those projects generally are 18 months or less; option periods may be proposed for out-years. Because the nature and scope of each proposed research project will vary, it is anticipated that the size and duration of each award will vary. Start dates will vary depending upon when proposals/applications were submitted and reviewed and the negotiation process. However, no proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission to Grants.gov.

PIs seeking additional or continuation funding must submit new pre-proposals/pre-applications and be invited to submit full proposals/applications.

See the General Submission Instructions, Section II.C.5., for additional information regarding the research and related budget.

C. Mechanisms of Support

The USAMRMC executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the government will be a matter of negotiation prior to award.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC[4] 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

IV. ELIGIBILITY INFORMATION

A. Eligible Applicants

Awards are made to organizations only. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 1, for general eligibility information.

NOTE: In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed so long as they are permitted under the sponsoring agreement between the federal government and the specific FFRDC.

The USAMRMC is committed to supporting small businesses. Small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals/applications submitted through the BAA.

B. Eligible Investigators

Eligible investigators include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Investigators are cautioned that awards are made to organizations, not individuals.

C. Cost Sharing or Matching is not required under this announcement.

D. Other Review Information

The following information will be reviewed prior to the award of a contract or assistance agreement:

1. "Exclusions" Identified in SAM

To protect the public interest, the federal government ensures the integrity of federal programs by striving to conduct business only with responsible organizations. The USAMRMC uses the "Exclusions" within the Performance Information functional area of the System for Award Management (SAM); data from the Federal Awardee Performance and Integrity Information System, a component within SAM, is used to verify that an organization is eligible to receive

[4] United States Code

federal awards. More information about the "Exclusions" reported in SAM is available at https://www.sam.gov/. Refer to the General Submission Instructions, Section II.A., for additional information.

2. Conflicts of Interest

All conflicts of interest (COIs) or potential COIs must be disclosed with the proposal/application submission, along with a plan to resolve them. All COIs on the part of an organization or individual investigators that could bias the research project must be resolved prior to the award of a contract or assistance agreement. Refer to the General Submission Instructions, Appendix 1, for additional information.

3. Review of Risk

The following areas may be reviewed in evaluating the risk posed by the an applicant: Financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental statutes and regulations.

4. Subcontracting Plan

If the resultant award is a contract that exceeds $650,000 and the offeror is a large business or an institution of higher education (other than Historically Black Colleges and Universities/Minority Institutions), the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

V. PROPOSAL/APPLICATION SUBMISSION INFORMATION

A. Where to Obtain the Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number **W81XWH-BAA-15-1**.

Submission is a two-step process requiring both: (1) Pre-proposal/pre-application submission through eBRAP (https://eBRAP.org/); and (2) full proposal/application submission through Grants.gov (http://www.grants.gov/).

B. Pre-Proposal/Pre-Application Submission and Content

Submission of a pre-proposal/pre-application is required and must be submitted through eBRAP (https://eBRAP.org/). If the USAMRMC is interested in receiving a full proposal/application, the PI will be sent an invitation to submit via eBRAP.

Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, a PI should not change the title or research objectives after the pre-proposal/pre-application is submitted. A PI and organization identified in the pre-proposal/pre-

application should be the same as those intended for the full proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.

The organization, Business Official, and PI must register in eBRAP before submitting a pre-proposal/pre-application. 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. The organization, Business Officials, and PIs must all be registered and affiliated in eBRAP. (See *eBRAP User Guide* at *https://ebrap.org/eBRAP/public/UserGuide.pdf*.)

Pre-proposals/pre-applications may be submitted at any time prior to the BAA closing date. Pre-proposals/pre-applications should describe specific ideas or projects that pertain to any of the areas described under "Program Description" in this BAA. A pre-proposal/pre-application must include a brief description of the scientific methods and design to address the problem as described below. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a pre-proposal/pre-application. ***DO NOT include any proprietary information in the pre-proposal/pre-application.***

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs. Refer to the General Submission Instructions, Section II.B., for additional information on pre-proposal/pre-application submission.

- **Tab 1 – Application Information:** Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

- **Tab 2 – Application Contact:** Enter contact information for the PI and the organization's Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 form. The Business Official must either be named or invited in order for the pre-proposal/pre-application to be submitted. If the organization's Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

  NOTE: The eBRAP system does not require an approval of the pre-proposal/pre-application by the PI's organization.

- **Tab 3 – Collaborators and Conflicts of Interest (COI):** To enable the USAMRMC to avoid COIs during the screening and review processes, list the names of all scientific participants in the proposed research project, including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees.

  Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in the research proposed or

assisting in any pre-proposal/pre-application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these Military Facility personnel cannot be involved in the review process and/or with making funding recommendations.***

Refer to the General Submission Instructions, Appendix 1, for additional information. For questions related to COIs, contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Required Files**

  NOTE: Figures, charts, graphs or other additional material will not be accepted during the pre-proposal/pre-application process.

  Provide responses in the appropriate data fields for the following in eBRAP. Fields cannot be blank. eBRAP will truncate characters exceeding the limit specified for each data field. Enter "none" if there is no information to be included.

  - Problem to Be Studied (4,000 character limit, including spaces).
  - Theoretical Rationale, Scientific Methods, and Design (4,000 character limit, including spaces).
  - Significance and/or Uniqueness of the Proposed Effort (4,000 character limit, including spaces).
  - Military Relevance and Impact (4,000 character limit, including spaces).
  - Brief Description of Animal and/or Human Use (4,000 character limit, including spaces).
  - Plans and Strategy for Translation, Implementation, and/or Commercialization (4,000 character limit, including spaces).

  Upload document(s) as individual PDF files. eBRAP will not allow a document to be uploaded in the Required Files tab if the number of pages exceeds the limits specified below.

  - Budget Summary: Upload as "BudgetSummary.pdf." – Complete the two-page Budget Summary Form (available for download in eBRAP) as instructed.
  - PI and Key Personnel Biographical Sketches (five-page limit per individual): Bold or highlight publications relevant to the proposed project.

  Refer to the General Submission Instructions, Section II.C.4., for detailed information.

- **Tab 5 – Submit Pre-Application:** This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

C. Notification of Pre-Proposal/Pre-Application Screening Results

The USAMRMC scientists or outside experts will screen pre-proposals/pre-applications for technical merit and programmatic considerations. Based on the screening of the pre-proposal/pre-application, a PI may be invited to submit a full proposal/application.

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit full proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposals/pre-applications. Within 120 days of submission, PIs should receive email notification via eBRAP regarding disposition of their pre-proposals/pre-applications.

D. Full Proposal/Application Submission Content and Forms

A proposal/application will not be accepted unless the PI has received an invitation to submit.

If the USAMRMC is interested in receiving a full proposal/application, the PI will receive an invitation to submit via email from eBRAP. An invited full proposal/application must be submitted through Grants.gov (http://www.grants.gov/). It should be submitted within 90 days of the PI's receipt of an invitation to submit. Agency receipt of a full proposal/application will be acknowledged by an email sent to the PI via eBRAP. The proposal/application log number for the full proposal/application will be the same number as used for the pre-proposal/pre-application, e.g., BA15xxxx.

The organization and PI will have registered in eBRAP during the pre-proposal/pre-application stage. This will permit an organization's representatives and PIs to be able to view and modify Grants.gov proposal/application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated in eBRAP.

Proposal/Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. Modification of proposal/application components is permitted at any time ***within 5 calendar days of proposal/application submission to Grants.gov, i.e., the verification period.*** If modification and/or verification are not completed by the end the verification period, the proposal/application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the proposal/application (Section VII.A., Rejection).

Each proposal/application submission must include the completed submission package of forms and attachments provided in Grants.gov for this BAA. The submission package is to be submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). Refer to the General Submission Instructions, Section II, for submission information.

Proprietary information should ***only be included if necessary*** for evaluation of the proposal/application. Conspicuously and legibly mark any proprietary information that is included in the proposal/application.

The PI should receive disposition regarding the proposal/application via an email from eBRAP within 180 days of submission.

E. Grants.gov Proposal/Application Package Components

The Grants.gov submission package includes the following components (refer to the General Submission Instructions, Section II.C., for additional information on proposal/application submission):

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

2. **Attachments Form**

- **Attachment 1: Project Narrative (20-page limit)**: Upload as "ProjectNarrative.pdf." – There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

  A detailed description of the research to be undertaken should be submitted. This should include the areas provided below, and address their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. Evaluation of the proposed research will be influenced by the adequacy of this information. Literature references and curriculum vitae will be shown in separate addenda entries.

  The following general outline should be followed:

  - **Background:** Provide a brief statement of ideas and theoretical reasoning behind the proposed study. Describe previous experience most pertinent to this proposal/application. Cite relevant literature references. Include discussion of any findings (if available) from relevant pilot or preliminary work or any related work underway. For development of devices and technologies, provide an intellectual property plan as part of the supporting documentation.
  - **Hypothesis:** State the hypothesis to be tested and the expected results. For development of devices and technologies, discuss the technical feasibility of the proposed project including background of the problem, previous and current solutions, similar projects previously undertaken, and related development activities.
  - **Technical Objectives:** State concisely the question to be answered by each research objective.
  - **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance. For development of devices and technologies, discuss the timelines and provide a commercial strategy plan for the technology being developed.

- **Military Significance:** State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.
- **Public Purpose**. If appropriate, provide a concise, detailed description of how this research project will benefit the general public.
- **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For synthetic chemistry proposal/applications, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses. For development of devices and technologies, discuss the engineering/technical design to achieve the project goals demonstrating the feasibility of the proposed product development. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them. For studies involving human subjects, describe recruitment plan and access to populations. The proposal/application should describe a plan for data access. (Access to subjects and data is the sole responsibility of the investigator.) As relevant, describe plans for addressing issues unique to working with military populations.
- **Additional Information:** If human and/or animal subjects are included in the research, proposals/applications may be submitted without human and/or animal use protocols and institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human and/or animal use are not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.

  PIs and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers, or laboratory animals until applicable regulatory documents are approved by the USAMRMC to ensure that DoD regulations have been met.

  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
  - Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
  - If applicable, indicate time required for submission and/or approval of documents (e.g., Investigational New Drug and Investigational Device Exemption) to the U.S. Food and Drug Administration or appropriate government agency.

- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC Human Research Protection Office (HRPO); this does not include the additional time required for local Institutional Review Board (IRB) review and approval.
- For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC Animal Care and Use Review Office (ACURO); this does not include the additional time required for local Institutional Animal Care and Use Committee (IACUC) review and approval.
- Refer to the General Submission Instructions, Appendix 5, for additional regulatory information.

- **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.***
  - **Bibliography & References Cited:** List the references in the order they appear in the proposal/application narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities and Other Resources:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the USAMRMC. Indicate if a government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.
  - **Equipment:** Include a description of existing equipment to be used for the proposed research project.
  - **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 attached.
  - **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. A letter for each organization involved in the project should be provided.
  - **Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost.
  - ***If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility,***

or a DoD activity embedded with a civilian medical center), special requirements apply. A DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application. (Refer to the General Submission Instructions, Section II.C.4., for additional information.)

- **Joint Sponsorship:** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- **Intellectual Property (if applicable):** All software and data first produced under the award are subject to a federal purpose license in accordance with applicable requirements of the Federal Acquisition Regulations (FAR) Part 27, Defense FAR Supplement Part 227, and DoD Grant and Agreement Regulations (Chapter I, Subchapter C of Title 32 Code of Federal Regulations).
  - **Background and Proprietary Information:** Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the government and indicate whether the applicant will require a waiver of the federal purpose license.
  - **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating organizations.
  - **Commercialization Strategy:** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to market, competitors and management team. Discuss the significance of this development effort, when it can be anticipated and the potential commercial use for the technology being developed.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf." The abstract is vitally important to both the scientific peer and programmatic review processes. It is paramount that the investigator submits a technical abstract that fully describes the proposed work. The abstract must contain the title of the project and the name of the PI. Do not include figures or tables in the abstract. Use only characters available on a standard QWERTY keyboard. Spell out all Greek or other non-English letters. Abstracts of all funded proposals/applications may be posted; ***therefore, proprietary information should not be included in the abstract.***

The structured technical abstract should be clear and concise, and at a minimum, provide the following information:

- **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State concisely the specific aims of the study.
- **Study Design:** Briefly describe the study design.
- **Relevance:** Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.

- **Attachment 4: Statement of Work (SOW) (two-page limit):** Upload as "SOW.pdf." The SOW outlines and establishes the PI and an organization's performance expectations for which the USAMRMC may provide funding. Unlike the general objectives, which are agreed to in a grant or cooperative agreement SOW, the contract SOW sets rather specific goals and conditions for each year of the contracted project. The PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW will be incorporated into the award document and, as such, is subject to release under Freedom of Information Act.

  A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award. Allow at least 2 to 3 months for the USAMRMC Office of Research Protections' regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

- **Attachment 5: Impact/Outcomes Statement (one-page limit):** Upload as "Impact.pdf." Explain the potential impact of the research in the field, the significance of this impact, and when it can be anticipated. Explain how the results of this research are expected to impact the intended beneficiaries. Expound upon the dual (military and public) purpose for the research, as appropriate. For development of devices and technologies, include the potential translation, implementation, and/or commercial use for the product/technology being developed.

- **Attachment 6: Data- and Research Resource-Sharing Plan (one-page limit):** Upload as "Sharing.pdf." Describe how unique and/or final research data will be shared with the research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or

research resource-sharing plan. For projects involving clinical trials, PIs may be required to register their clinical trials on Clinicaltrials.gov (https://clinicaltrials.gov/). For projects involving TBI, PIs may be required to report data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system (http://fitbir.nih.gov/). If the project includes systems biology (SB)-related research, the PI may be required to make the SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (https://sysbiocube-abcc.ncifcrf.gov). Refer to the General Submission Instructions, Appendix 3, for additional information.

- **Attachment 7: Translation, Implementation, and/or Commercialization Strategy*, if applicable*:** Upload as "Trans_Imp_Comm.pdf." Describe the translation, implementation, and/or commercialization plan. The plan should include intellectual property, market size, market potential, cost of research and development, strengths and weaknesses, barriers to market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential translation, implementation, and/or commercial use for the technology being developed.

- **Attachment 8: Conflicts of Interest*, if applicable*:** Upload as "COI.pdf." Provide details with the proposal/application submission of all organizational or individual investigator COIs, or potential COIs, along with a plan to resolve them. A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be resolved.

  Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these individuals cannot be involved in the review process and/or with making funding recommendations.***

  Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to the General Submission Instructions, Appendix 1, for additional information.

- **Attachment 9: Collaborating DoD Military Facility Budget Form(s)*, if applicable*:** Upload as "MFBudget.pdf." If a Military Facility will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the Full Announcement page in Grants.gov), including a budget justification, for each Military Facility as instructed. Refer to the General Submission Instructions, Section II.C.8., for detailed information.

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

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf."

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (five-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 Submission Instructions, Section II.C.4., for detailed information.

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

NOTE: Proposals/Applications from **federal agencies** must include in their budget justifications a **Federal Financial Plan**. Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** must comply with special requirements. Refer to the General Submission Instructions, Section II.C., Research & Related Budget, for detailed information.

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

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

F. Verification of Grants.gov Proposal/Application in eBRAP

Organizational representatives and PIs can view their proposals/applications as submitted through Grants.gov within a period of 5 calendar days of proposal/application submissions to Grants.gov, i.e., ***the verification period***. This will enable applicants to make modifications to proposals/applications until the end of the verification period, prior to scientific and programmatic evaluations.

After proposal/application submission to Grants.gov, eBRAP will retrieve and validate the submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the proposal/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 proposal/application components. ***If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID.*** Refer to the General Submission Instructions, Section II.C., for more information.

G. Data Universal Number System Numbers, Commercial and Government Entity Code, and System for Award Management

An applicant organization and any subaward organization must have Data Universal Number System (DUNS) numbers (issued by Dun and Bradstreet) before submitting a

proposal/application to Grants.gov. In addition, an applicant organization must have a Commercial and Government Entity (CAGE) Code. Also, the organization must be registered as an Entity with the System for Award Management (SAM) and have an "Active" status before submitting a proposal/application through Grants.gov or receiving an award from the federal government.

Refer to the General Submission Instructions, Section II, for additional information.

H. Submission Dates and Times

The BAA is an open and continuous announcement for a 12-month period, from October 1 through September 30 of each year. A pre-proposal/pre-application can be submitted at any time throughout the 12-month period. A full proposal/application may only be submitted if the PI has submitted a pre-proposal/pre-application and received an invitation to submit. No pre-proposal/pre-application or full proposal/application can be submitted to this BAA after September 30, 2015, at 11:59 p.m. Eastern Time. If an invited proposal/application is not submitted by September 30, 2015, it will have to be submitted under the FY16 BAA (to be posted to Grants.gov on October 1, 2015).

I. Intergovernmental Review

This BAA is not subject to Executive Order (EO) 12372.

J. Funding Restrictions

There are no specified funding limitations identified for a proposal/application submitted under this BAA, except for the "Special Investment Areas/Innovation Funding" area of interest (refer to Section II.A.9., for more information). Refer to the General Submission Instructions, Section II.C.4, "Research & Related Budget," for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

K. Other Submission Requirements

Proposals/applications must be submitted electronically to Grants.gov. Refer to the General Submission Instructions, Appendix 2, for detailed Grants.gov formatting guidelines.

VI. PROPOSAL/APPLICATION REVIEW AND SELECTION INFORMATION

All invited proposals/applications are evaluated by USAMRMC scientists, other federal agency representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof, using a two-tier review process. The first tier is **peer review** of proposals/applications against established criteria for determining technical merit. The second tier is **programmatic review** based on established criteria for determining relevance to the mission of the USAMRMC and its programs.

All USAMRMC review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign agreements to protect the confidentiality of the information that proposal/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 by military personnel or employee of the Federal government is a crime in accordance with 18 USC 1905.

A. Peer and Programmatic Review

1. Peer Review: To determine technical merit, all proposals/applications will be evaluated according to the following scored criteria, which are listed in descending order of importance:

- **Research Objectives:** The degree to which the stated objectives are clear, valid, and logical. For development of devices and technologies, the degree to which the performance objectives are plausible; the proposed effort demonstrates familiarity with the historical background of the problem and previous/current solutions; and the awareness of similar projects previously undertaken and related activities. The extent that the proposed research projects demonstrate an innovative approach and relate to the Research Areas of Interest identified in Section II.A.
- **Scientific Design Excellence:** The degree to which proposed plans, methods, techniques and procedures are feasible, clear, valid, adequately referenced, and state-of-the-art. The merit of the statistical features of the study. The extent to which literature searches were used to document the strengths of the proposed project. For development of devices and technologies, the feasibility of the proposed product/technology development plan; how well the engineering/technical design is likely to achieve the goals indicated; adequacy of the engineering/design solutions; and how well the perceived engineering/design strengths and flaws are addressed.
- **Impact/Outcomes:** The potential impact of the research in the field, the significance of this impact, and when it can be anticipated. For development of devices and technologies, the potential translation, implementation, and/or commercial use for the product/technology being developed.
- **PI and Key Personnel Qualifications:** The qualifications, capabilities, and experience of the proposed PI and other key personnel to demonstrate that the proposed staff has the knowledge, technical expertise, and management skills to achieve the proposed objectives as well as the time available for the percentage of efforts indicated for the project.
- **Facilities:** The proposed facilities and equipment, or unique combinations of these, to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.
- **Budget:** The degree to which the budget reflects the actual needs of the proposed work, is thoroughly detailed and fully justified so that the government can evaluate and determine the cost to be allocable, allowable and reasonable, and commensurate with the complexity and nature of the research proposed.

2. Programmatic Review: To make funding recommendations, the following criteria will be used by programmatic reviewers:

- Scientific peer review results
- Military relevance (mission, health, medicine, and beneficiaries)
- Portfolio balance
- Programmatic priorities

NOTE: Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals/ applications must address a military-relevant health problem responsive to one of the Research Areas of Interest identified in Section II.A.

B. Submission Review Dates

This is a continuously open announcement through September 30, 2015; therefore, reviews occur throughout the year. Pre-proposals/pre-applications may be submitted and will be evaluated at any time throughout the 12-month period noted above. An invited full proposal/application should be submitted within 90 days of the PI's receipt of an invitation to submit. No pre-proposal/pre-application or full proposal/application may be submitted under this BAA after September 30, 2015. If an invited proposal/application is not submitted by September 30, 2015, it will have to be submitted under the FY16 BAA (to be posted to Grants.gov October 1, 2015). No proposal/application received under this BAA will be considered for funding after 24 months from the date of submission.

C. Proposal/Application Selection Process

After the two-tier evaluation, proposals/applications recommended for funding may be prioritized. A prioritized listing of alternates (deferred decisions) may also be prepared, when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise.

If selected for funding, the award may also be dependent upon the organization providing adequate additional regulatory documentation, such as human subjects/anatomical substances/use of cadavers protocols and approvals, animal subjects protocols and approvals, and environmental information. The award may also be dependent upon additional supporting administrative and budgetary information.

D. Notification of Proposal/Application Review Results

Each PI and organization will receive email notification via eBRAP of the funding recommendation. Notifications should be sent within 180 days of submission. Each PI will receive a peer review summary statement on the strengths and weaknesses of the proposal/application.

A recommended for funding notification is NOT an authorization to begin performance or a guarantee of an award. Awards are contingent upon availability of funding, adequacy of supporting documentation submitted, fulfillment of all requirements, and upon completion of successful negotiations. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. Awards may be issued at any time throughout the year.

VII. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the proposal/application:

- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget form contains only zeros.

B. Modification

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

C. Withdrawal

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

- Federal agency personnel involved in the review process and/or with making funding recommendations are named as being involved in the research proposed or found to have assisted in the pre-proposal/pre-application or proposal/application processes, including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.***

- Inclusion of any employee of USAMRMC review contractors in pre-proposals/pre-applications or full proposals/applications for funding without adequate plans to resolve conflicts of interest. Refer to General Submission Instructions, Appendix 1, 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 PI does not meet the eligibility criteria as described in this BAA.
- The full proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
- The full proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.

D. Withhold

Proposals/Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Contracting or Grants Officer for a determination of the final disposition of the proposal/application.

VIII. AWARD ADMINISTRATION INFORMATION

A. Award Notice

The PI should receive disposition regarding the full proposal/application via an email from eBRAP within 180 days of submission. A recommended for funding notification is NOT an authorization to begin performance nor a guarantee of an award.

The awarding agency will be the USAMRAA. The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the federal government. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. No commitment on the part of the government should be inferred from discussions with any other individual.

Awards will be made at any time throughout the year and are contingent upon availability of funding, adequacy of supporting documentation submitted, fulfillment of requirements, and completion of successful negotiations. No proposal/application submitted under this BAA will be considered for funding after 24 months from the date of submission to Grants.gov.

Refer to the General Submission Instructions, Appendix 3, for additional information.

B. Administrative Requirements

Refer to the General Submission Instructions, Appendix 3, for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Submission Instructions, Appendix 4, for general information regarding national policy requirements.

D. Reporting Requirements

Refer to the General Application Instructions, Appendix 3, for general information on reporting requirements.

E. Changes of Principal Investigator and Organization

Refer to the General Submission Instructions, Appendix 3, for general information on changes to PIs and organizational transfers.

IX. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to BAA content or submission requirements as well as questions related to the submission of the pre-proposal/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. Eastern Time. 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 full proposal/application submission through the 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 BAA 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.

X. OTHER INFORMATION

A. Recipient Qualification

Refer to the General Submission Instructions, Appendix 1, for general information on required qualifications.

In addition to other information provided herein, by submitting a proposal/application and accepting an award, the organization is: (1) certifying that the investigators' credentials have been examined; (2) verifying that the investigators are qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed. Investigators include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Investigators are cautioned that awards are made to organizations, not individuals. A PI must submit a proposal/application through an organization in order to receive support.

Should the PI of a funded project leave the award organization, both the PI and organization must contact the USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify the USAMRAA prior to the PI leaving the organization.

B. Proprietary Information

Do not include any proprietary information in the pre-proposal/pre-application or full proposal/application. Proprietary information should ***only be included*** in the full proposal/application ***if necessary for evaluation purposes.*** Abstracts of all funded proposals/applications may be posted; ***therefore, proprietary information should not be included in the abstract.***

Conspicuously and legibly mark any proprietary information that is included in the full proposal/application. Identify any proprietary information that will be provided to the government and whether the applicant will request a waiver of government purpose rights.

C. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See Proposal/Application Submission Checklist below.)
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to send attachments.
- Inability to locate attachment forms. (Select "Search Grants" at http://www.grants.gov and enter W81XWH-BAA-15-1 in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the "View Grant Opportunity" screen, select "Full Announcement." The forms will be listed on the following screen.)

- Use of “illegal” characters in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

XI. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Submission Package Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete 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."	
	Statement of Work: Upload as Attachment 4 with file name "SOW.pdf."	
	Impact/Outcomes Statement: Upload as Attachment 5 with file name "Impact.pdf."	
	Data- and Research Resource-Sharing Plan: Upload as Attachment 6 with file name "Sharing.pdf."	
	Translation, Implementation, and/or Commercialization Strategy (if applicable): Upload as Attachment 7 with file name "Trans_Imp_Comm.pdf."	
	Conflicts of Interest (if applicable): Upload as Attachment 8 with file name "COI.pdf."	
	Collaborating DoD Military Facility Budget Form(s) (if applicable): Upload as Attachment 9 with the file name "MFBudget.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	Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. Complete form as instructed.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form (if applicable)	Complete form as instructed.	