

General Application Instructions

Version 20160210

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Table of Contents

I. HELPFUL INFORMATION 2

- A. Tips for Success 2
- B. Current Funding Opportunities 2
- C. Receiving Emails from the CDMRP, eBRAP, and Grants.gov 2
- D. Agency Contacts 3

II. REGISTRATION AND SUBMISSION INFORMATION 4

- A. Registration Requirements..... 4
- B. Content and Form of Pre-Application Submission..... 6
- C. Content and Form of Full Application Submission 8
- D. Applicant Verification of Grants.gov Submission in eBRAP 24

APPENDIX 1 Qualification and Eligibility Information 25

APPENDIX 2 Formatting Guidelines 27

APPENDIX 3 Grants.gov requirements 28

APPENDIX 4 Administrative Information and Requirements..... 30

APPENDIX 5 National Policy Requirements..... 37

APPENDIX 6 Regulatory Requirements..... 40

APPENDIX 7 Acronym List 47

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

B. Current Funding Opportunities

To view all funding opportunities currently offered through the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov (<http://www.grants.gov/>) search using the Catalog of Federal Domestic Assistance (CFDA) Number 12.420. Information may be found on the CDMRP website at <http://cdmrp.army.mil/funding/> and on the CDMRP's electronic Biomedical Research Application Portal (eBRAP) website at <https://ebrap.org/ebrap/public/program.htm>. To receive email notifications when CDMRP funding opportunities are released, subscribe to program-specific news and updates under the "Email Subscriptions" section on eBRAP's homepage (<https://ebrap.org/eBRAP/programSubscription/Subscribe.htm>). Email notifications of funding opportunities are sent as a courtesy and should not be used as the sole source of notification; applicants should subscribe on Grants.gov to receive notifications of updates and new grant opportunity postings (<http://www.grants.gov/web/grants/manage-subscriptions.html>).

To ensure accurate referencing, please verify that the eight-digit (numeric) version number on the title page of this document matches the version number of the Program Announcement/Funding Opportunity found in Section VI.A. "Program Announcement/Funding Opportunity and General Application Instructions Version" of the Program Announcement.

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. Also, use the same email address when submitting both the pre-application to eBRAP and the full application to Grants.gov.

On occasion, the Grants.gov application package may be updated or changed. The applicant must use the latest version of the Grants.gov application package; applications submitted with a different version of the Grants.gov application package will be rejected 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 specific Program Announcement/Funding Opportunity or by responding to the Grants.gov prompt *when first downloading the Grants.gov application package.***

D. Agency Contacts

- 1. CDMRP Help Desk:** Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to submission of 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 U.S. Federal holidays).

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II. REGISTRATION AND SUBMISSION INFORMATION

Application submission is a two-step process requiring both (1) pre-application submission through eBRAP (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). General registration information is provided below. For detailed instructions, refer to the eBRAP User Guide (<https://ebrap.org/eBRAP/public/UserGuide.pdf>) for eBRAP registration, and www.grants.gov for Grants.gov registration.

All pre-application and application components must be submitted by the deadlines stipulated in the Program Announcement/Funding Opportunity. Material submitted after the deadlines, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet any of the deadlines will result in application rejection.



Submission of applications from U.S. Federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. See [Section II.C.4.](#), Research & Related Budget.



For specific guidance regarding changes to the Principal Investigator (PI) or organization, refer to the Program Announcement/Funding Opportunity.

The CDMRP encourages all PIs to participate in a digital identifier initiative through ORCID, Inc. Registration for a unique Open Researcher and Contributor Identification (ORCID) can be done online at <http://orcid.org/>.

A. Registration Requirements

Electronic Biomedical Research Application Portal (eBRAP) Registration

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and throughout the period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements, and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as to ensure proper ordering as specified in the Program Announcement/Funding Opportunity.

Detailed eBRAP registration instructions are available in the eBRAP User Guide at <https://ebrap.org/eBRAP/public/UserGuide.pdf>.



eBRAP does not confirm the accuracy of file content!

To submit a pre-application, PIs must be registered in eBRAP.

PIs are encouraged to start the registration processes for eBRAP early to ensure that there is sufficient time for completion prior to the submission deadline. There is no grace period.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on Standard Form 424 Research and Related (SF424 (R&R)) Form of the Grants.gov application package submitted to Grants.gov. PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

During eBRAP registration, the PI must request to be affiliated with his/her organization from the list of organizations already registered with eBRAP. If the PI’s organization is not already registered with eBRAP, then the PI must invite an Authorized Organizational Representative (AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline in order for the pre-application to be submitted. However, before the full application submission deadline, the organization’s eBRAP registration must be complete to allow for processing, viewing, and modifying of the Grants.gov application package components.

During pre-application submission, the PI must identify a Business Official from the list of Business Officials registered with eBRAP. If the PI’s Business Official is not already registered with eBRAP, the PI must invite the Business Official to register. This invitation to register must be sent prior to the pre-application deadline, but the Business Official does not need to complete the registration for the pre-application to be submitted. However, the Business Official’s registration must be completed prior to the full application deadline to allow the Business Official to view/modify the full application files in eBRAP after Grants.gov submission.

During pre-application submission, the PI must select the performing organization (site at which the PI will perform the proposed work) and contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited to allow submission of the pre-application.

The Grants.gov application package submitted to Grants.gov may be viewed in eBRAP until the end of the application verification period. After eBRAP has processed the Grants.gov application, PIs will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the Grants.gov application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. See the Program Announcement/Funding Opportunity for specific full application submission and application verification deadlines.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP.

If a revised Project Narrative or Budget Form document is needed, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID found in Block 4.c. of the SF424 (R&R) Form prior to the full application submission deadline.

Grants.gov Registration: Please refer to [Appendix 3](#) for more information.

B. Content and Form of Pre-Application Submission



For specific instructions regarding content of the pre-application submission components, refer to the Program Announcement/Funding Opportunity.



All pre-application components must be submitted through eBRAP (<https://eBRAP.org/>) by the deadline specified in the Program Announcement/Funding Opportunity. Click on “Submit” and “Confirm Submission” to complete the pre-application submission.

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

Tab 1 – Application Information: Enter the application information as described in eBRAP before continuing the pre-application. Click on “Save.”

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 SF424 (R&R) Form). Depending on screen resolution, scrolling horizontally may be necessary to locate the box to Invite an AOR to register the performing and/or contracting organization. Click the “Add Organizations to this Pre-application.” The Business Official must either be selected from the eBRAP list or invited to allow 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.**

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

Note: CDMRP does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Unless otherwise noted in the Program Announcement/Funding Opportunity (e.g., Partnering PIs), applicants should assign the role of each participant in accordance with the participant’s respective involvement in the project.

No member of the Programmatic Panel may be named as being involved in the research proposed or found to have assisted in the pre-application or application processes. Refer to the specific Program Announcement/Funding Opportunity for a link to the list of Programmatic Panel members.

If formal collaboration with Military Facility personnel is planned (i.e., included in the 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 having any role in the preparation, research, or other duties for submitted applications. The identities of the peer and programmatic review contractors can be found at <http://cdmrp.army.mil/about/2tierRevProcess.shtml>. Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (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.

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). Click on “Save.”

Tab 5 – Pre-Application Files: Upload all documents as PDF as specified in the Program Announcement/Funding Opportunity. Documents should conform to the formatting guidelines outlined in [Appendix 2](#). Click on “Upload.”

- eBRAP will truncate characters exceeding the limit specified for each data field as specified in the Program Announcement/Funding Opportunity.
- 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 Program Announcement/Funding Opportunity.

Tab 6 – Submit Pre-Application: Enter eBRAP password and click the “Submit” button. Click the “Confirm Submission” button to complete the pre-application submission. *This finalizes the pre-application process.*



The pre-application is not submitted until Tab 6 is complete. Pre-applications not completed are left in DRAFT status.

Following completion of pre-application submission, the status of the pre-application 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. Check the status of the pre-application. There are no grace periods.*

C. Content and Form of Full Application Submission

Each application submission must include the completed Grants.gov application package of forms associated with the specific Program Announcement/Funding Opportunity 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.*** Rejected applications must be resubmitted using a new Grants.gov application package and a supported version of Adobe Reader prior to the application submission deadline. 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/>. All contributors to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.

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.

Any modifications to the Project Narrative or Budget Form require submission of a changed/corrected Grants.gov application package to Grants.gov prior to the application submission deadline. The Project Narrative and Budget Form cannot be modified during the application verification period.

The application submission deadline and the end of the application verification period in eBRAP are stated on the title page of the respective Program Announcement/Funding Opportunity. See [Section II.D.](#), Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

The Grants.gov application components are listed below:

1. SF424 (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 Grants.gov 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 Grants.gov application package must be resubmitted with the “Changed/Corrected Application” box selected.
- **Block 2 – Date Submitted.** Enter the date the 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.** Enter in your eBRAP log number.

Figure 1. Enter your eBRAP log number in Block 4a.

The image shows a form with three input fields. The first field is labeled "4. a. Federal Identifier" and is circled in red. The second field is labeled "b. Agency Routing Identifier" and the third is labeled "c. Previous Grants.gov Tracking ID".

- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/correct applications, enter the Grants.gov tracking number for the original 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 United States, 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-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, 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 application. If outside the United States, 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.

- **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 (SFLLL) to disclose lobbying activities pursuant to Title 31 of the 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 automatically completed upon submission of the Grants.gov application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.

2. Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form.

Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to view, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If the Project Narrative or budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.*** See [Section II.D.](#), Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

Each attachment in the Attachments Form 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 listed in the Program Announcement/Funding Opportunity and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible 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 Grants.gov 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.



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 Program Announcement/Funding Opportunity.



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 resolution of 100-150 dots per inch.

The following must be included as attachments:

Attachment 1: Project Narrative: Named “ProjectNarrative.pdf.” The Project Narrative is the main body of the 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. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Submission of a Project Narrative that exceeds the page limit specified in the Program Announcement/Funding Opportunity will result in administrative rejection of the application.

Attachment 2: Supporting Documentation: Combine and attach as a **single PDF file named “Support.pdf.”** Include only supporting documentation as indicated in the Program Announcement/Funding Opportunity. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the application may be administratively withdrawn. *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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.*

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



For a list and descriptions of required supporting documents, refer to the Program Announcement/Funding Opportunity.

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.

The Technical Abstract will be posted publicly and will be included in the award agreement.

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.

The Lay Abstract will be posted publicly and will be included in the award agreement.

Attachment 5: Statement of Work (SOW): Named “SOW.pdf.” The SOW is an outline of specific aims of the proposed research project that establishes the project milestones during the performance period of the award. The SOW should contain sufficient detail to be informative as a standalone document. There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit.

SOW Format: PIs are strongly encouraged to use the suggested SOW format stated in the Program Announcement/Funding Opportunity. Templates for SOW formats are available on the eBRAP “Program Announcement & Forms” page (<https://ebrap.org/eBRAP/public/Program.htm>). The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined step-by-step as they relate to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); description of research with animals, human anatomical substances, and/or human subjects or cadavers to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. As applicable, estimated times to complete each task should include time for local and U.S. Army Medical Research and Materiel Command (USAMRMC) regulatory review and approval, as shown below. Refer to [Appendix 6](#) for additional information regarding regulatory review.
 - For studies involving human subjects, include a subtask that allows 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, include a subtask that allows 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.
- Briefly describe the methods to be used.

- 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 timelines required for regulatory approvals relevant to human subjects review (e.g., Investigational New Drug and Investigational Device Exemption) by the U.S. Food and Drug Administration or other Government agency.



For specific instructions regarding SOW content, refer to the Program Announcement/Funding Opportunity.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the Program Announcement/Funding Opportunity (e.g., “Impact.pdf,” “Innovation.pdf,” “Training.pdf,” “Transition.pdf,” etc.).



For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the Program Announcement/Funding Opportunity.

3. 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 User Name provided by eBRAP into the data field labeled “Credential, e.g., agency login” (Figure 2).

Figure 2. PI’s eBRAP User Name

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:
 * Last Name: Suffix:
 Position/Title: Department:
 Organization Name: Division:
 * Street1:
 Street2:
 * City: County/ Parish:
 * State: Province:
 * Country: USA: UNITED STATES * Zip / Postal Code:
 * Phone Number: Fax Number:
 * E-Mail:
 Credential, e.g., agency login:

Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. Use of this document is optional. The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF

format prior to attachment. Page limitations will be notated in the Program Announcement/Funding Opportunity. Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- 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/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.

4. Research & Related Budget

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs, and period of performance, refer to the Program Announcement/Funding Opportunity. The budget and budget justification should include sufficient detail for the Government to determine whether the proposed costs are 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 I.* At the time of application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

If the budget fails eBRAP validation or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.

No budget will be approved by the Government exceeding the cost limit stated in the specific Program Announcement/Funding Opportunity or using an indirect rate exceeding the organization's negotiated rate.

Budget Regulations and Restrictions:

The following must be utilized in developing the budget:

- **Maximum Obligation:** 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. Foreign currency exchange rates for recipients performing research outside of the United States will be determined at the time of application submission.
- **Administrative and Cost Principles:** Recipients 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)
 - Provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant and Agreement Regulations," Parts 26, 28, 37, and 1125
 - Federal Acquisition Regulation (FAR) Part 31
 - Defense FAR Supplement Part 231

Terms and conditions of awards made after December 26, 2014 may reflect DoD's further implementation of 2 CFR Part 200.

- **Pre-Award Costs:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the 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. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

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 in anticipation of an award 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 or in the absence of appropriations. The

Government expects the 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 within the approved time frame or in any way adversely affect the conduct of the project.

- **Cost of Preparing Applications:** The cost of preparing applications in response to a Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications may be an allowable cost that can be included in the indirect/facilities and administrative cost as specified in the organization's applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for recipients performing research outside of the United States will be determined at the time of application submission.



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 Form following the instructions below. Begin by entering the organizational Data Universal Numbering System (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 application.***



For all Federal agencies or organizations collaborating with Federal agencies applying to this Program Announcement/Funding Opportunity, special restrictions apply to the budget and are described below.

For Federal Agencies: An 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: An application from an organization that includes 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) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Section 7 below. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

Section A: Senior/Key Person

- **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.

- **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 and, therefore, these salaries should not be included in the requested budget.*
- **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.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the 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, other Federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
- **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.
- **Requested Salary:** Enter the amount of salary requested for this budget period. *For most Federal agencies, funding cannot be applied toward Federal salaries and, therefore, these salaries should not be included in the requested budget.*
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the 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).

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

Section C: Equipment Description. Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per unit acquisition cost which equals or exceeds the lesser of (a) \$5,000 or (b) the recipient's or the subrecipient's capitalization threshold for financial statement purposes. 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:

- Special test equipment to be fabricated for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- 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:

- Costs to attend scientific/technical meetings per year as specified in the Program Announcement/Funding Opportunity: 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.
- 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.
- Costs to attend required meetings (if applicable): Include the meeting name if identified in the Program Announcement/Funding Opportunity and a statement in the budget justification confirming that the PI will attend the required meeting.
- Funds from this award may not be used to cover approved travel costs for DoD military and civilian employees. All travel costs of DoD military and civilian employees that are approved for this project will be paid directly by the Government rather than funding from this award.

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:** Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment. 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.

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.
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:** Whether or not 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. **Automated Data Processing (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 item 1 above, Materials and Supplies regarding the purchase of computers.
 5. **Subaward/Consortium/Contractual Costs:** Include the total funds 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.

If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.



All direct and indirect costs of any subaward must be included in the direct costs of the primary award. No budget will be approved by the Government exceeding the cost limit stated in the Program Announcement/Funding Opportunity or using an indirect rate exceeding the organization's negotiated rate.

- 6. Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
- 7. 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.
- 8-10. 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.

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.

In accordance with 2 CFR 200.414, a non-Federal entity that has never received a negotiated indirect cost rate, may elect to charge a de minimis rate of 10% of modified total direct costs. Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the non-Federal entity chooses to negotiate for a rate.

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 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, use the demerit cost rate of 10%. 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 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.

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 so the Government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

5. 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.

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

Complete a separate detailed Research & Related Budget 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/subrecipient organization, and attach to the R & R Subaward Budget Attachment(s) Form.



All direct and indirect costs of any subaward must be included in the direct costs of the primary award. The primary award (including the direct and indirect costs of any subawardees) will not exceed the cost limit stated in the Program Announcement/Funding Opportunity.

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

7. Collaborating with DoD Military Facilities Form

This section summarizes the requirements of U.S. Army Medical Research Acquisition Activity (USAMRAA) Assistance/Procurement Advisory Notice (APAN) 15-01 (http://www.usamraa.army.mil/pages/pdf/APAN_15-01-Supporting_Military_Facilities_Costs_when_Performing_Collaborative_Research.pdf) which addresses requirements and procedures when a Military Facility will be a collaborator in performance of an extramural project.

Budget Form: Complete a separate “**Collaborating DoD Military Facility Budget Form,**” for each Military Facility involved in the project. The form is available for download on the eBRAP “Funding Opportunities and Forms web page (<https://eBRAP.org>). Do not complete the Grants.gov R&R Subaward Budget Attachment Form.

Direct Costs:

- **Salaries:** Include the positions/titles/ranks and levels of effort of all DoD civilian and military personnel planned to work on the extramural project, whether or not salaries/fringe benefits are proposed. Salaries/fringe benefits may be reimbursed, either directly by the Federal government to the facility or through the extramural award to the facility, but only under certain limited circumstances, which will be discussed during negotiations. Applicant organizations can provide their personnel to work on the project; those costs should not be included here but on the organizations Research and Related Budget Form (Sections A and B).
- **Travel:** Include costs to be incurred by DoD civilian and military personnel. However, note that these costs cannot be reimbursed through the extramural award. They can only be funded directly by the Federal government to the facility. Some restrictions apply. Processes will be discussed during negotiations.
- **Consultants, Equipment, Materials, Supplies, Other, Etc.:** Include all anticipated direct costs. The Military Facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the Military Facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should not be included on the applicant organization’s Research and Related Budget Form and not included on this form.
- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DoD-established reimbursement rates (e.g., IRB fees, IACUC fees, etc.), the Military Facility’s Resource Management (RM) office (or equivalent) must provide details of how the proposed rates/fees were determined. Rates/fees should be included in the Other Direct Costs line of the Research & Related Budget Form (Section F.8-10).

- **Indirect Costs:** If an indirect cost rate is proposed, include documentation to support the rate (i.e., cost pool(s) and what items are included in each pool). The Military Facility should consult with its RM office (or equivalent) for assistance in determining a rate.
- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Subaward/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5.).

Budget Justification: Include a budget justification for each year, for each Military Facility. A description of services or materials that are to be provided by the collaborating Military Facility is required. The Military Facility researcher(s) should coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. 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. In addition, the Military Facilities' direct and indirect costs to be supported when performing collaborative research with the extramural organization must meet the requirements of the DoD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: 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 all costs to be incurred in performance of the Military Facility's portion of the research project. When "direct funded," these funds **will not** be included in the award amount to the contractor or recipient.

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRMC RM office is not able to "direct fund" the Military Facility, the funds may be placed on the award and the contractor or recipient may provide award funds to the Military Facility. If known at the time of submission, the Military Facility, in conjunction with the applicant organization, should 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 and 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.

PARC Approval: Prior to the issuance of any award utilizing the funding method described above, written approval from the USAMRAA's Principal Assistant Responsible for Contracting (PARC) will be required. PARC approval is not required at the time of submission. The justification will be considered by the USAMRAA Grants Officer in consultation with the applicant organization and the Contracting Officer's Representative/Grant Officer's Representative (COR/GOR). If considered to be justified, the Contracting/Grants Officer will seek PARC approval.

Technology Transfer: The Military Facility researcher(s) should also coordinate with his/her technology transfer office, when applicable. The facility may require that a cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) be executed between the facility and the contractor or recipient before work between the organization can begin or funds can be provided to the Military Facility. The CRADA (or other

instrument) is not required at the time of application submission. A timeline for execution of the document will be established during negotiations.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline. The full application submission deadline and the end of the application verification period in eBRAP are stated in the specific Program Announcement/Funding Opportunity.

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 assistance or procurement awards, if it is a prior recipient of such awards; (2) have a satisfactory record of integrity and business ethics; and (3) meet the standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Part 22.415.

The USAMRMC 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

Effective January 1, 2016, prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000) over the period of performance, the Federal awarding agency is required to review information regarding the recipient that is available through the Federal Awardee Performance and Integrity Information System (FAPIS). The recipient may submit comments to FAPIS about any information that the Federal awarding agency reported to FAPIS for consideration by the Federal awarding agency in making future Federal awards to the recipient.

In accordance with the Office of Management and Budget's (OMB's) final guidance implementing the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (hereafter referred to as "section 872"), as that statute applies to grants, effective January 1, 2016, recipients that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000, or for existing awards that are terminated on or after January 2, 2016 due to material failure to comply with the Federal awards terms and conditions, are required to provide information to FAPIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually the information about the criminal, civil, and administrative proceedings that section 872(c) describes. Reference Federal Register Notice, Vol. 80, No. 140, Wednesday, July 22, 2015.

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 Program Announcement/Funding Opportunity 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.
- **Government Agencies within the United States:** 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.

C. Conflict of Interest

- All awards must be free of Conflicts of Interest (COIs), as defined at 32 CFR 32.42, that could bias the research results. Prior to award, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Grants Officer that a COI cannot be adequately managed.

D. Post-Employment Restrictions

- There are certain post-employment restrictions on former Federal officers and employees as defined in Section 207 of Title 18 United States Code. Post-employment restrictions may exist if a former Federal officer or employee participates in the proposed project; the situation should be discussed with the USAMRMC legal staff (301-619-6598) prior to expending time and effort in preparation of an application.

APPENDIX 2

FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ among 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](#). All contributors to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.
- **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-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 and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.
- **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. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Program Announcement/Funding Opportunity (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:** Individual attachments should be no larger than 20 MB. *If the file size for the entire Grants.gov 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

GRANTS.GOV REQUIREMENTS

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.*** Registering early is advised.

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

If business is conducted with the Federal Government on a continuing basis, it is likely that some of the required actions have already been completed, e.g., obtaining a DUNS number or registration as an Entity in the SAM. Detailed information, links, 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:

1. DUNS Number

The applicant organization and all subrecipient/subawardee organizations must have a DUNS number. A DUNS number is a unique 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>). Organizations located outside of the United States can request and register for a DUNS number on line via web registration (<http://fedgov.dnb.com/webform>). Web registration can take 1-2 business days.

2. SAM Registry

The applicant organization must be registered as an Entity with the System for Award Management (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>. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. 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>.***

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

3. 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 advances 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 organization is located or by connecting to Form AC135 (<http://www.dlis.dla.mil/nato/ObtainCAGE.aspx>). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

4. Authorized Organizational Representative (AOR)

Each organization must have an AOR who is registered with Grants.gov (individual PIs do not register with Grants.gov). An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before application submission, the AOR must be registered 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 registration 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.

APPENDIX 4

ADMINISTRATIVE INFORMATION AND REQUIREMENTS

A. Disclosure of Proprietary Information

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

Proprietary information submitted in an application may be disclosed outside the Government for the sole purpose of evaluation. Evaluators must agree that proprietary information in the application will be used for evaluation purposes only and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act (FOIA).

Applications for funded projects will be subject to public release under the FOIA to the extent that they are incorporated into an award document; 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 application.

C. Award Notices

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement/Funding Opportunity will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

An assistance agreement (grant or cooperative agreement) 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 United States, 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. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA 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 Grants Officer is the official authorizing documents.

D. Inquiry Review

If an application is not recommended for funding, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 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 application. Inquiries in response to funding recommendations should be submitted to the USAMRAA Grants Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. The determination of an error in the review process is not a guarantee of funding. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA 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 (www.ntis.gov) to acquire information of existing research to avoid duplication of scientific and engineering effort.

F. Freedom of Information Act Requests

The 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 Act (www.usdoj.gov/oip/index.html).

When an FOIA request asks for information contained in a successful application that has been incorporated into an award document, the submitter 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 submitter 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 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 statements must be included in all information releases:

- (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 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-16-1-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 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 include the above statements and adhere to the above regulations, when required, 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:

- Technical/Scientific:
 - Quarterly and/or annual progress reports
 - Monthly progress reports (at the discretion of the Grants Officer)
 - Final progress report
 - In-progress reviews
 - Quad Chart: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at

[https://cdmrp.org/Program Announcements and Forms/](https://cdmrp.org/Program_Announcements_and_Forms/), and completed for submission with the application.

USAMRMC research progress reporting requirements and instructions can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting.

- Fiscal (SF425 “Federal Financial Report”):
 - Quarterly and/or annual reports
 - Monthly (at the discretion of the Grants Officer)
 - Final report
- Regulatory:
 - Research Involving Human Subjects: For DoD awards that include funding to support research with human subjects, the USAMRMC’s 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 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 the 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 Application Information

The CDMRP shares application information with other Federal funding agencies (e.g., NIH, National Science Foundation, Department of Veterans Affairs) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on CDMRP-funded awards including awardee information and published results are shared on the Defense Technical Information Center (DTIC).

K. Sharing of Data and Research Resources

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities), and to the public. The expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the Program Announcement/Funding Opportunity. This includes all data and research resources generated during the project's period of performance as annotated in the assistance agreement:

- **Unique Data** 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. (Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)
- **Final Research Data** 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. (Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)
- **Research Resources** 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, methods, laboratory equipment and machines. (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. Depending on the Program Announcement/Funding Opportunity, the PI may be required to participate in the following:

- **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 (<https://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 (<https://sysbiocube-abcc.ncifcrf.gov/>).

Application information may be shared with other Federal funding agencies (e.g., NIH, National Science Foundation, Department of Veterans Affairs) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the web and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Updates on awards, including awardee information and published results are shared on DTIC.

For additional information on CDMRP's expectations and policies for data-sharing, refer to the document titled "Policy on Sharing Data & Research Resources," available on eBRAP under Resources and Reference Material at <https://ebrap.org/eBRAP/public/Program.htm>. For unique data sharing guidelines and requirements, refer to the instructions in the specific Program Announcement/Funding Opportunity.

L. Post-Award Organization and Principal Investigator Changes

Transfer of Award to New Organization: Unless restricted by the specific Program Announcement/Funding Opportunity, a change in organizational affiliation will be considered on a case-by-case basis by the USAMRAA Grants Officer. If approved, the PI's original organization will be required 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. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location.

Change in Principal Investigator: Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

M. Property/Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property acquired 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 acquired by for-profit organizations will conditionally vest in the organization subject to the requirements of the DoDGAR, 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 acquired 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 USC 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, but the U.S. 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.

O. J-1 Visa Waiver

Each organization, including organizations located outside of the United States, are responsible for ensuring that the personnel associated with any 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 United States under a J-1 Visa.

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: travel.state.gov/visa/temp.

APPENDIX 5

NATIONAL POLICY REQUIREMENTS

National policy requirements applicable to the DoD awards are listed in Appendices A and B to Part 22 of the 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>). For additional regulatory requirements regarding safety, surety, and environmental requirements, and for use of animal and human subjects in research, refer to this General Applications Instructions, Appendix 6.

A. Certification

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 31 USC 1352 and is a prerequisite for making or entering into an award over \$100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of SF424 (R&R) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

- (1) No Federally 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 SFLLL (Disclosure of Lobbying Activities), 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.

B. Representations

In accordance with DoD appropriations, recipients who are corporations are required to complete the representations below and submit with each application. The form for completion and submission 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

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 applicant 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.

In accordance with DoD appropriations, the following representation is required. The applicant, by its signature on the SF424 (R&R), represents:

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

By submission of its 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.

National Policy Requirements

The recipient must comply with the following requirements, as applicable. References entitled “Effective November 2015: National Policy Requirements” are available on <http://www.usamraa.army.mil/>.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections

APPENDIX 6

REGULATORY REQUIREMENTS

A. Safety and Environmental Requirements

Based on recent changes to DoD compliance requirements (DA PAM 385-69, DA PAM 385-10, 32 CFR 651 6 Sep 2012), provisions previously required 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, Biological Select Agents or Toxins, specific chemical agent(s), or pesticides outside of an established laboratory. The USAMRMC Office of Surety and Environment will identify any need for compliance review and documents must be submitted upon request.

Additional information is available at:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_resources.environmental

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

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

PIs and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until 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

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations 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 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 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 subject 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 a determination from the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. 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. All amendments or modifications must also be reviewed prior to initiation for the life of the award. 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 (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

2. 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 or human anatomical substances obtained from 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/index.cfm?pageid=research_protections.overview). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. **HRPO must review the use of post-mortem specimens for compliance with the Army Cadaver Use 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 human cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

3. Research Involving the Secondary Use of Data/Specimens

All USAMRMC supported research involving the secondary use of human data, records, human tissue, or human specimens (hereafter referred as data/specimens) must be reviewed for compliance with Federal and DoD human subjects protection requirements and approved by the ORP prior to implementation. USAMRMC ORP HRPO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DoD funded research protocol. HRPO review, approvals, and determinations for specimen research are based upon the nature of the research, the source of the data/specimens, use and/or disclosure of identifiable health information, privacy and confidentiality protections, and whether the individual providing the data/specimens allowed the use of their data/specimens for research. For additional guidance and instructions on HRPO review of any DoD funded research activities involving access, use, and analysis of data/specimens, investigators should submit the HRPO Submission Form for Secondary research found on the ORP HRPO website.

https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo

4. Research Involving Human Subjects,



In addition to local IRB review, investigators must submit all USAMRMC-funded research protocols involving human subjects for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate the 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 should only be used as a guide; it is not intended to be a source for human subjects protection regulations. Questions regarding applicable human subjects 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 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 that additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific DoD laws and requirements governing research involving human subjects. These laws and requirements 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/index.cfm?pageid=research_protections.hrpo. 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 HRPO submission and review of research involving human subjects 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 completed appropriate training in the protection of human subjects. Documentation confirming completion of appropriate training may be required during the regulatory review process.

(3) **Informed Consent Form:** The following must appear in the consent form:

- A statement that the U.S. 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 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 for 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 is a much narrower definition of ***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-usarmmc.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 monitor’s 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 his or her observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and documentation of human subjects protection training for the research monitor must be provided. There should be no apparent COI, 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.

1. 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.

2. **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.

3. **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.

C. Clinical Trial Registry

PIs are required to register clinical trials individually on <http://clinicaltrials.gov/> using a Secondary Protocol ID number designation of “CDMRP-eBRAP Log Number” (e.g., CDMRP-PC16#####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “CDMRP-eBRAP Log Number-A, B, C, etc.” (e.g., CDMRP-PC16#####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see <http://prsinfo.clinicaltrials.gov/>, click on “Support Materials (including data element definitions)”) 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.

D. Research Involving Recombinant DNA Molecules

The recipient assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at <http://www4.od.nih.gov/oba>.

APPENDIX 7

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
APAN	Assistance/Procurement Advisory Notice
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CDC	Centers for Disease Control and Prevention
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
DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDI	Department of Defense Instruction
DoDGAR	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
eBRAP	electronic Biomedical Research Application Portal
EIN	Employer Identification Number
EPLS	Excluded Parties List System
F&A	Facilities and Administrative
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FITBIR	Federal Interagency TBI Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
G&A	General and Administrative
GSA	General Services Administration
HIPAA	Health Information Portability and Accountability Act
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health
OHRP	Office for Human Research Protection

OMB	Office of Management and Budget
ORP	Office of Research Protections
PARC	Principal Assistant Responsible for Contracting
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SB	Systems Biology
SFLLL	Standard Form LLL
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others
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