General Application Instructions

Fiscal Year 2015

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

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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 to the Program Announcement/Funding Opportunity for specific instructions.

B. Current Funding Opportunities

To view all funding opportunities currently offered by 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. Additional 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 a sole source of notification; applicants should subscribe on Grants.gov to receive notifications of new grant opportunity postings and updates on (http://www.grants.gov/web/grants/manage-subscriptions.html) for official postings of funding opportunities.

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

To help ensure that all email correspondence is delivered correctly and is not treated as spam by email programs, keep your email address up to date in eBRAP and Grants.gov and place the following domains into your safelist: army.mil, us.army.mil, *.mail.mil, eBRAP.org, and grants.gov. 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 prompt *provided by Grants.gov 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
   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 identified 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 one 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.B.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 ORCID identifier can be done online at http://orcid.org/.

A. Registration Requirements

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 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. 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 (SF-424) 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 his/her 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.

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 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 the application verification deadlines.

Specific information must be identical between the pre-application and the full application for eBRAP to process an application. Mismatched information may delay the availability of the application during the application verification period. For the PI to view/modify files, the PI's name and email address in the eBRAP pre-application submission must match the information provided in SF-424 of the Grants.gov application package. For the Business Official to view/modify files, the Business Official's name and email address in the eBRAP pre-application submission must match the information provided in SF-424 of the Grants.gov application package.

If a revised Budget Form or Project Narrative 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 identified in block 4.c of SF-424 prior to the full application submission deadline.

Grants.gov Registration

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 actions have already been completed, e.g., obtaining a Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management (SAM). Detailed information, 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 goes through the validation process. Foreign registrants in SAM must have a NATO CAGE Code (NCAGE) assigned. 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.asp). 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; the Authorized Organizational Representative (AOR) is required to register. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before submitting an application, an organization representative must register to submit on behalf of the organization at Grants.gov (http://apply07.grants.gov/apply/OrcRegister).

An AOR must first register with the Grants.gov credential provider at http://apply07.grants.gov/apply/OrcRegister to obtain a username and password. Once an AOR has completed the Grants.gov 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.

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. Remember to select the "Submit" and the "Confirm Submission" buttons to complete the pre-application submission.

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

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

Tab 2 – Application Contacts: Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424). The Business Official must either be selected from the eBRAP list or invited in

order for the pre-application to be submitted. **If the Business Official cannot be found in eBRAP, an invitation must be sent to him/her to register in eBRAP.**

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

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 review panel (e.g., Integration Panel, Steering Committee, Joint Program Committee) for the program to which an application is submitted 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 programmatic review 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 in applications for funding. The peer review contractor is SRA International, Inc. The programmatic review contractor is Leidos, Inc. Applications that include names of personnel from any of these companies will be administratively withdrawn unless plans to mitigate 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).

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

- 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 password in the space provided next to "Enter Your Password Here" and click the "Submit" button. Click the "Confirm Submission" button to complete the pre-application submission.

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.***

C. Content and Form of 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/.

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 revised 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 cover of the respective Program Announcement/Funding Opportunity. See Section II.D., Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

The application consists of the following components:

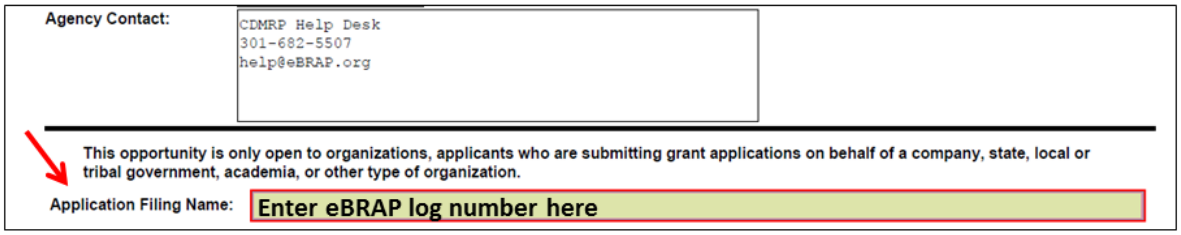
1. eBRAP Log Number

During the pre-application process, each submission will be assigned a unique log number by eBRAP. The corresponding Grants.gov application package must be submitted using this unique eBRAP log number to avoid delays in application processing. Enter the eBRAP log number in one of two ways:

System-to-System Entry: If a system-to-system interface with Grants.gov is being used, enter the eBRAP log number acquired during the pre-application process into the **Submission Title** field.

Manual Entry: Fill in the **Application Filing Name** on the first screen of the Grants.gov Application Package (Figure 1) using only the **eBRAP log number** (e.g., AR15####, BC15####) assigned during the pre-application process.

Figure 1. Manual Entry of eBRAP log number in Grants.gov Application Package



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

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in this 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.** This box will be populated by Grants.gov for an original application.
- **Block 4b. Agency Routing Identifier.** Not applicable.

- **Block 4c. Previous Grants.gov Tracking ID.** For changed/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.

3. 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.***

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

Attachment 5: Statement of Work (SOW): Named "SOW.pdf." The SOW 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.

SOW Format: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. 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 5 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 3 to 4 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.).

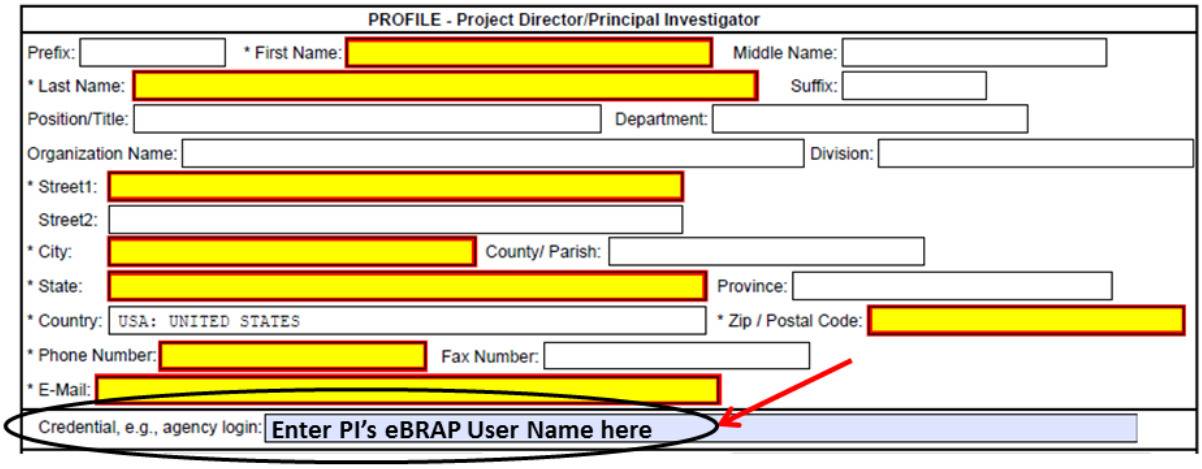
For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the Program Announcement/Funding Opportunity.

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

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

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

Figure 2. PI's eBRAP User Name



Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. Use of this document is optional. The National Institutes of Health 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.

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.

5. 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 1.*** At the time of application submission to Grants.gov, the Authorized Organizational Representative is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

If the budget fails eBRAP validation, 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.
- **Administrative and Cost Principles:** Recipients will be required to comply with the following, as applicable:
  - 2 Code of Federal Regulations (CFR) part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the Department of Defense's (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," other than parts 21, 22, 32, 33, and 37.
  - 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, without the Government's prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the 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.

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 must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Section 8 below.

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

- 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 one or more scientific/technical meetings per year: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be well justified and is subject to approval.

- 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.

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

Section F: Other Direct Costs

1. **Materials and Supplies:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing $5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.
2. **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
3. **Consultant Services:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
4. **ADP/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates. See item 8 below, "Other Expenses" 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.

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

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

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

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

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

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

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

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

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

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

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

6. Project/Performance Site Location(s) Form

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

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

Complete a separate detailed Research & Related Budget 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.

8. Collaborating with DoD Military Facilities Form

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

A description of services or materials that are to be provided by the collaborating Military Facility is required. Applicant organizations must provide sufficient detail and justification to enable the Federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

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

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

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

If extraordinary circumstances exist whereby the USAMRMC RM office is not able to "direct fund" the Military Facility, the recipient may provide award funds to the Military Facility. The Military Facility, in conjunction with the applicant organization, must provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility, the associated costs, when the activities will

take place, why "direct funding" is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc. If approved, these funds would be included in the award amount to the recipient. Prior approval from the U.S. Army Medical Command, Principal Assistant Responsible for Contracting, is required under this funding method.

A cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) must be utilized for the recipient to provide award funds 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, 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, Part 22.415.

The U.S. Army Medical Research and Materiel Command (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

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 U.S. Army Medical Research Acquisition Activity 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

- Post-Employment Conflict of Interest: There are certain post-employment restrictions on former Federal officers and employees as defined in Section 207 of Title 18 United States Code and Federal Acquisition Regulation (FAR), Part 3.104-4(c). If an applicant believes a post-employment restriction or conflict of interest may exist, the situation should be discussed with the USAMRMC legal staff (301-619-6598) prior to expending time and effort in preparation of an application.

- Organizational and Individual Investigator Conflicts of Interest: All conflicts of interest on the part of an organization or individual investigators must be resolved prior to the award of an assistance agreement. All awards must be free of any conflicts of interest that could bias the research projects.

FAR Part 9.5 will be used as a guide in analyzing and resolving organizational conflicts of interest relating to an award. An organizational conflict of interest may result when factors create an actual or potential conflict of interest, or when the nature of the work to be performed creates an actual or potential conflict of interest on future acquisitions and some restrictions on future activities of the recipient may be required. All conflicts or potential conflicts of interest must be disclosed, along with a plan to mitigate the conflict, with the application submission. An award may not be made if it is determined by the Grants Officer that a conflict of interest cannot be avoided or mitigated.

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.
- **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.
- **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

ADMINISTRATIVE INFORMATION AND REQUIREMENTS

A. Defense Health Program Authority

As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. This includes DHP medical RDT&E Congressional Special Interest (CSI) appropriations. Within the U.S. Army Medical Research and Materiel Command (USAMRMC), the Congressionally Directed Medical Research Programs (CDMRP) is responsible for the day-to-day execution functions of these DHP medical RDT&E CSI appropriations and performs activities such as developing funding opportunities for applications, conducting peer and programmatic review of applications, and overall program management. Other USAMRMC organizations are responsible for the issuance of awards (assistance agreements or contracts), resource management, and a variety of follow-on program management, legal and regulatory review, and compliance actions.

B. 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.

C. Marking of Proprietary Information

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

D. Award Notices

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

The DoD's purpose is to support and stimulate the recipient's activities, not to assume direction, prime responsibility, or a dominant role in the project. Consistent with this concept, the dominant role and primary responsibility reside with the recipient for the project as a whole, although specific tasks and activities may be shared among the recipient and the DoD.

When the Grants Officer determines that the DoD will be performing normal stewardship activities (i.e., reviewing progress reports, reviewing financial reports, performing site visits, providing program oversight activities), a grant award will be made. Grant awards are the most frequent form of award. However, when the Grants Officer determines that substantial involvement is expected between the DoD and the recipient when carrying out the project, such as through collaboration, participation, or intervention in the project, a cooperative agreement award will be made. The award type, along with the start date, will be determined during the negotiation process.

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

Only an appointed USAMRAA 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.

E. 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.

F. 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.

G. Freedom of Information Act Requests

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

When a FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the 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.

H. 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 Department of Defense (DoD). The requirement with specific language will be included in the award notice. Below is an example:

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

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

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

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

Failure to include the above statements and adhere to the above regulations, when required, may result in loss of funding.

I. 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
  - Final progress report
  - Quad Chart: The Quad Chart template is a one-page PowerPoint file that must be downloaded from eBRAP at https://cdmrp.org/Program_Announcements_and_Forms/, completed, and saved as a PDF file using Adobe Acrobat Reader.

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

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

J. 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.

K. Sharing of Application Information

The CDMRP shares application information with other Federal funding agencies (e.g., National Institutes of Health [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).

L. Sharing of Data and Research Resources

It is the intent of the CDMRP that data and research resources generated by CDMRP-funded research be made available to the research community (which includes both scientific and consumer advocacy communities), other funding agencies, and to the public. The CDMRP's expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the CDMRP. This includes all data and research resources generated during the project's period of performance as annotated in the assistance agreement:

- **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.

For additional information on CDMRP's expectations and policies for data-sharing, refer to the document titled "Congressionally Directed Medical Research Programs: Policy on Sharing Data and 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.

M. 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 and will require the PI's original organization to agree to relinquish the award. The new organization will be required to resubmit the entire proposal/application on behalf of the PI, including regulatory documentation. 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 made at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

N. Property/Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property purchased with Government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the Government. Title to equipment or other tangible property purchased by for-profit organizations will conditionally vest in the organization subject to the requirements of the Department of Defense Grant and Agreement Regulations, Part 34.21. However, if the award is subsequently transferred to a new organization, the DoD reserves the right to require the transfer of equipment purchased with the award funds to the Federal Government or to an eligible third party

O. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, 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.

P. 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 4

NATIONAL POLICY REQUIREMENTS

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

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 5.

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 Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into an award over $100,000. Complete Standard Form LLL (SFLLL) (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of SF-424 (R&R) (Application for Federal Assistance).

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 Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

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

C. Assurances

Assurances will be required as applicable in each award document as award terms and conditions, as follow:

1. Nondiscrimination

By accepting funds under this award, the recipient assures that it will comply with applicable provisions of the following national policies prohibiting discrimination:

a. On the basis of race, color, or national origin, in Title VI of the Civil Rights Act of 1964 (42 USC 2000d, et seq.), as implemented by DoD regulations at Title 32 of the Code of Federal Regulations, Part 195 (32 CFR 195).

b. On the basis of sex or blindness, in Title IX of the Education Amendments of 1972 (20 USC 1681, et seq.), as implemented by DoD regulations at 32 CFR 196.

c. On the basis of age, in the Age Discrimination Act of 1975 (42 USC 6101, et seq.) as implemented by Department of Health and Human Services regulations at 45 CFR 90.

d. On the basis of handicap, in Section 504 of the Rehabilitation Act of 1973 (29 USC 794), as implemented by Department of Justice regulations at 28 CFR 41 and DoD regulations at 32 CFR 56, and the Architectural Barriers Act of 1968 (42 USC 4151, et seq.).

2. Debarment and Suspension

The recipient assures that it will comply with the requirements regarding debarment and suspension in Subpart C of the OMB guidance in 2 CFR 180, as implemented by the DoD in 2 CFR 125. The recipient shall communicate the requirement to comply with Subpart C to persons at the next lower tier with whom the recipient enters into transactions that are "covered transactions" under Subpart B of 2 CFR 180 and the DoD implementation in 2 CFR 1125.

3. Environmental Standards

By accepting funds under this award, the recipient assures that it will:

Comply with applicable provisions of the Clean Air Act (42 USC 7401, et seq.) and Clean Water Act (33 USC 1251, et seq.), as implemented by Executive Order 11738 (3 CFR, 1971-1975 comp., p. 799) and Environmental Protection Agency (EPA) rules at 40 CFR 32. In accordance with the EPA rules, the recipient further agrees that it will:

a. Not use any facility on the EPA's List of Violating Facilities in performing any award that is nonexempt under 40 CFR 15.5 (awards of less than $100,000, and certain other awards, exempt from the EPA regulations), as long as the facility remains on the list.

b. Notify the awarding agency if, in performing this award, it intends to use a facility on the List of Violating Facilities or that the recipient knows has been recommended to be placed on the List of Violating Facilities.

c. Notify the awarding agency of any impact this award may have on:

   i. The quality of the human environment, and provide help the agency may need to comply with the National Environmental Policy Act (at 42 USC 4321, et seq.) and to prepare Environmental Impact Statements or other required environmental documentation. In such cases, the recipient agrees to take no action that will have an adverse environmental impact (e.g., physical disturbance of a site such as breaking of ground) until the agency provides written notification of compliance with the environmental impact analysis process.

   ii. Coastal barriers, and provide help the agency may need to comply with the Coastal Barriers Resource Act (16 USC 3501, et seq.), concerning preservation of barrier resources.

   iii. Any existing or proposed component of the National Wild and Scenic Rivers system, and provide help the agency may need to comply with the Wild and Scenic Rivers Act of 1968 (16 USC 1271, et seq.).

4. Drug-Free Workplace

By accepting funds under this award, the recipient assures that it will comply with the "Governmentwide Requirements for Drug-Free Workplace (Grants)" requirements specified by Department of Defense Grant and Agreement Regulations (DoDGAR) Part 26, Subpart B (or Subpart C, if the recipient is an individual) of 32 CFR 26 (2004), which implements sec.5151-5160 of Drug-Free Workplace Act of 1988 (41 USC 701, et seq.).

5. Officials Not to Benefit

No member of or delegate to Congress, or resident commissioner, shall be admitted to any share or part of this award, or to any benefit arising from it, in accordance with 41 USC 22.

6. Preference for U.S.-Flag Air Carriers

Travel supported by U.S. Government funds under this award shall use U.S.-flag air carriers (air carriers holding certificates under 49 USC 41102) for international air transportation of people and property to the extent that such service is available, in accordance with the International Air Transportation Fair Competitive Practices Act of 1974 (49 USC 40118) and the interpretative guidelines issued by the Comptroller General of the United States in the March 31, 1981, amendment to Comptroller General Decision B138942.

7. Cargo Preference

The recipient assures that it will comply with the Cargo Preference Act of 1954 (46 USC 1241), as implemented by Department of Transportation regulations at 46 CFR 381.7, which require that at least 50 percent of equipment, materials, or commodities procured or otherwise obtained with U.S. Government funds under this award, and which may be transported by ocean vessel, shall be transported on privately owned U.S.-flag commercial vessels, if available.

8. Campus Access for Military Recruiting and Reserve Officer Training Corps

The following requirement applies to institutions of higher education.

As a condition for receipt of funds available to the DoD under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 CFR 216) that has a policy or practice that either prohibits, or in effect prevents:

a. The Secretary of a Military Department from maintaining, establishing, or operating a unit of the Senior Reserve Officers Training Corps (in accordance with 10 USC 654 and other applicable Federal laws) at that institution (or any subelement of that institution);

b. Any student at that institution (or any subelement of that institution) from enrolling in a unit of the Senior Reserve Officers' Training Corps (ROTC) at another institution of higher education;

c. The Secretary of a Military Department or Secretary of Homeland Security from gaining access to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of military recruiting in a manner that is at least equal in

quality and scope to the access to campuses and to students that is provided to any other employer; or

d. Access by military recruiters for purposes of military recruiting to the names of students (who are 17 years of age or older and enrolled at that institution or any subelement of that institution); their addresses, telephone listings, dates and places of birth, levels of education, academic majors, and degrees received; and the most recent educational institutions in which they were enrolled.

If the recipient is determined, using the procedures in 32 CFR 216, to be such an institution of higher education during the period of performance of this agreement, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and cooperative agreements to the recipient, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of the award.

9. Radioactive Materials

The recipient assures that it will comply with 10 CFR 21. This regulation established procedures and requirements for implementation of Section 206 of the Energy Reorganization Act of 1974.

10. Requirements for Federal Funding Accountability and Transparency Act Implementation (2 CFR 170): Appendix A to Part 170 – Award Term

Reporting Subawards and Executive Compensation

a. Reporting of first-tier subawards.

i. Applicability. Unless you are exempt as provided in paragraph D. of this award term, you must report each action that obligates $25,000 or more in Federal funds that does not include Recovery funds (as defined in section 1512(a)(2) of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5) for a subaward to an entity (see definitions in paragraph e. of this award term).

ii. Where and when to report.

(a) You must report each obligating action described in paragraph a.1. of this award term to http://www.fsrs.gov.

(b) For subaward information, report no later than the end of the month following the month in which the obligation was made. (For example, if the obligation was made on November 6, 2015, the obligation must be reported by no later than December 31, 2015.)

iii. What to report. You must report the information about each obligating action that the submission instructions posted at http://www.fsrs.gov specify.

b. Reporting Total Compensation of Recipient Executives.

i. Applicability and what to report. You must report total compensation for each of your five most highly compensated executives for the preceding completed fiscal year, if:

(a) The total Federal funding authorized to date under this award is $25,000 or more;

(b) In the preceding fiscal year, you received:

(i) 80 percent or more of your annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(ii) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(c) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 USC 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.)

ii. Where and when to report. You must report executive total compensation described in paragraph b.1. of this award term:

(a) As part of your registration profile at https://www.sam.gov.

(b) By the end of the month following the month in which the award was made, and annually thereafter.

c. Reporting of Total Compensation of Subrecipient Executives.

i. Applicability and what to report. Unless you are exempt as provided in paragraph d. of this award term, for each first-tier subrecipient under this award, you shall report the names and total compensation of each of the subrecipient's five most highly compensated executives for the subrecipient's preceding completed fiscal year, if:

(a) In the subrecipient's preceding fiscal year, the subrecipient received:

(i) 80 percent or more of its annual gross revenues from Federal procurement contracts (and subcontracts) and Federal financial assistance subject to the Transparency Act, as defined at 2 CFR 170.320 (and subawards); and

(ii) $25,000,000 or more in annual gross revenues from Federal procurement contracts (and subcontracts), and Federal financial assistance subject to the Transparency Act (and subawards); and

(b) The public does not have access to information about the compensation of the executives through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 USC 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. (To determine if the public has access to the compensation information, see the U.S. Security and Exchange Commission total compensation filings at http://www.sec.gov/answers/execomp.htm.

iii. Where and when to report. You must report subrecipient executive total compensation described in paragraph c.1. of this award term:

(a) To the recipient.

(b) By the end of the month following the month during which you make the subaward. For example, if a subaward is obligated on any date during the month of October of a given year (i.e., between October 1 and 31), you must report any required compensation information of the subrecipient by November 30 of that year.

d. Exemptions. If, in the previous tax year, you had gross income, from all sources, under $300,000, you are exempt from the requirements to report:

i. Subawards, and

ii. The total compensation of the five most highly compensated executives of any subrecipient.

e. Definitions. For purposes of this award term:

i. Entity means all of the following, as defined in 2 CFR 25:

(a) A Governmental organization, which is a State, local government, or Indian tribe;

(b) A foreign public entity;

(c) A domestic or foreign non-profit organization;

(d) A domestic or foreign for-profit organization;

(e) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

ii. Executive means officers, managing partners, or any other employees in management positions.

iii. Subaward:

(a) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

(b) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Subpart B–Audits, Sec.–.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

(c) A subaward may be provided through any legal agreement, including an agreement that you or a subrecipient considers a contract.

iv. Subrecipient means an entity that:

(a) Receives a subaward from you (the recipient) under this award; and

(b) Is accountable to you for the use of the Federal funds provided by the subaward.

v. Total compensation means the cash and noncash dollar value earned by the executive during the recipient's or subrecipient's preceding fiscal year and includes the following (for more information, see 17 CFR 229.402(c)(2)):

(a) Salary and bonus.

(b) Awards of stock, stock options, and stock appreciation rights. Use the dollar amount recognized for financial statement reporting purposes with respect to the fiscal year in accordance with the Statement of Financial Accounting Standards No. 123 (Revised 2004) (FAS 123R), Shared Based Payments.

(c) Earnings for services under non-equity incentive plans. This does not include group life, health, hospitalization, or medical reimbursement plans that do not discriminate in favor of executives and are available generally to all salaried employees.

(d) Change in pension value. This is the change in present value of defined benefit and actuarial pension plans.

(e) Above-market earnings on deferred compensation, which is not tax-qualified.

(f) Other compensation, if the aggregate value of all such other compensation (e.g., severance, termination payments, value of life insurance paid on behalf of the employee, perquisites or property) for the executive exceeds $10,000.

11. Financial Assistance Use of Universal Identifier and Central Contractor Registration (2 CFR 25): Appendix A to Part 25–Award Term

Central Contractor Registration and Universal Identifier Requirements

Note: The Central Contractor Registration process has been moved to the System for Award Management at www.sam.gov.

a. **System for Award Management (SAM), formerly Requirement for Central Contractor Registration (CCR).** Unless you are exempted from this requirement under 2 CFR 25.110, you as the recipient must maintain the currency of your information in the SAM until you submit the final financial report required under this award or receive the final payment, whichever is later. This requires that you review and update the information at least annually after the initial registration, and more frequently if required by changes in your information or another award term.

b. **Requirement for Data Universal Numbering System (DUNS) Numbers**. If you are authorized to make subawards under this award, you:

i. Must notify potential subrecipients that no entity (see definition in paragraph C of this award term) may receive a subaward from you unless the entity has provided its DUNS number to you.

ii. May not make a subaward to an entity unless the entity has provided its DUNS number to you.

c. **Definitions.** For purposes of this award term:

i. System for Award Management (SAM) (formerly Central Contractor Registration [CCR]) means the Federal repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM Internet site (http://www.sam.gov).

ii. Data Universal Numbering System (DUNS) number means the nine-digit number established and assigned by Dun and Bradstreet, Inc. (D&B) to uniquely identify business entities. A DUNS number may be obtained from D&B by telephone (866-705-5711) or the Internet (http://fedgov.dnb.com/webform).

iii. Entity, as it is used in this award term, means all of the following, as defined at 2 CFR 25(C):

(a) A Governmental organization, which is a State, local government, or Indian Tribe;

(b) A foreign public entity;

(c) A domestic or foreign non-profit organization;

(d) A domestic or foreign for-profit organization; and

(e) A Federal agency, but only as a subrecipient under an award or subaward to a non-Federal entity.

iv. Subaward:

(a) This term means a legal instrument to provide support for the performance of any portion of the substantive project or program for which you received this award and that you as the recipient award to an eligible subrecipient.

(b) The term does not include your procurement of property and services needed to carry out the project or program (for further explanation, see Sec.–.210 of the attachment to OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations").

(c) A subaward may be provided through any legal agreement, including an agreement that you consider a contract.

v. Subrecipient means an entity that:

(a) Receives a subaward from you under this award; and

(b) Is accountable to you for the use of the Federal funds provided by the subaward.

12. Trafficking Victims Protection Act

Trafficking in persons.

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

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

(a) Engage in severe forms of trafficking in persons during the period of time that the award is in effect;

(b) Procure a commercial sex act during the period of time that award is in effect; or

(c) Use forced labor in the performance of the award or subawards under the award.

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

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

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

(i) Associated with performance under this award; or

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

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

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

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

(a) Associated with performance under this award;

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

c. Provision applicable to any recipient.

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

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

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

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

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

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

i. **"Employee"** means either:

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

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

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

iii. **"Private entity"** means:

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

(b) Includes:

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

(ii) A for-profit organization.

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

APPENDIX 5

REGULATORY REQUIREMENTS

A. Safety and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, DA PAM 385-10, 32 CFR 651 6 Sep 2012), provisions previously 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 U.S. Army Medical Research and Materiel Command (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=researcher_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 USAMRMC 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.

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

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human 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. 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 3 to 4 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. 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 Human Subjects, Human Subjects Data, or Human Anatomical Substances

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

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (https://ebrap.org/eBRAP/public/Program.htm). This information 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 research involving human subjects, human subject data, or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

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

(2) Training: Personnel involved in human subjects research must have 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. Department of Defense is providing funding for the study.
- A statement that representatives of the DoD are authorized to review research records.

- In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.

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

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

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

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

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

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- Shall have the responsibility for promptly reporting 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 conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

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-PC15####). 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-PC15####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health database (see http://prsinfo.clinicaltrials.gov/, click on "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 6

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CCR	Central Contractor Registry
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
CSI	Congressional Special Interest
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
eBRAP	electronic Biomedical Research Application Portal
ECA	Environmental Compliance Assurance
EIN	Employer Identification Number
EPA	Environmental Protection Agency
EPLS	Excluded Parties List System
ET	Eastern Time
F&A	Facilities and Administrative
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FSP	Facility Safety Plan
FWA	Federalwide Assurance
FY	Fiscal Year
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
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
M	Million

MB	Megabyte
MPEG	Moving Picture Experts Group
MTF	Military Treatment Facility
NCAGE	NATO Commercial and Government Entity
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OHRP	Office for Human Research Protection
OMB	Office of Management and Budget
ORP	Office of Research Protections
PCR	Polymerase Chain Reaction
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
RDT&E	Research, Development, Test and Evaluation
ROTC	Reserve Officers' Training Corps
SAM	System for Award Management
SOW	Statement of Work
TIFF	Tagged Image File Format
TIN	Tax Identification Number
TVPA	Trafficking Victims Protection Act
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