General Submission Instructions

Broad Agency Announcement for Extramural Medical Research

Fiscal Year 2017

Department of Defense

U.S. Army Medical Research and Materiel Command

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This General Submission Instructions document must be read in conjunction with the Broad Agency Announcement, 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 Funding Opportunity Announcement/Broad Agency Announcement for specific instructions.

B. Current Funding Opportunity Announcement

The Fiscal Year 2017 U.S. Army Medical Research and Materiel Command's (USAMRMC) Broad Agency Announcement (BAA) can be found by searching Grants.gov (http://www.grants.gov/) using the Funding Opportunity Number **W81XWH-17-R-BAA1** or the Catalog of Federal Domestic Assistance (CFDA) number **12.420 Military Medical Research and Development.**

The execution management agent for this BAA will be the Congressionally Directed Medical Research Programs (CDMRP). Additional information may be found on the CDMRP's electronic Biomedical Research Application Portal (eBRAP) website at https://ebrap.org/eBRAP/public/index.htm.

The awarding agency will be the U.S. Army Medical Research Acquisition Activity (USAMRAA). The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the Federal Government for awards under this BAA.

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 safe list: 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 proposal/application package (hereinafter, application package) may be updated or changed. The applicant must use the latest version of the Grants.gov application package; proposals/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 BAA 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 BAA content or submission requirements, as well as questions related to submission of pre-proposals/pre-applications through eBRAP, should be directed to the CDMRP Help Desk, which is available Monday

through Friday from 8:00 a.m. to 5:00 p.m. Eastern time. Response times may vary depending upon the volume of inquiries. Be advised that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 301-682-5507

Email: help@eBRAP.org

2. **Grants.gov Contact Center:** Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays).

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

Email: support@grants.gov

II. REGISTRATION AND SUBMISSION INFORMATION

Application/proposal submission is a two-step process requiring both (1) pre-proposal/pre-application submission through eBRAP (https://eBRAP.org/) and (2) proposal/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.

Submission of proposals/applications from U.S. Federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. See Section II.D.5., Research & Related Budget.

For specific guidance regarding changes to the Principal Investigator (PI) or organization, refer to the BAA.

The CDMRP encourages all PIs to participate in a digital identifier initiative through ORCID, Inc. Registration for a unique Open Researcher and Contributor Identification (ORCID) 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-proposals/pre-applications electronically through a secure connection, to view and edit the content of their pre-proposals/pre-applications and full proposals/applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and throughout the period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov proposal/application submissions associated with them. eBRAP will validate Grants.gov proposal/application files against the specific BAA 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 proposal/application components for accuracy as well as to ensure proper ordering as specified in the BAA.

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-proposal/pre-application, PIs must be registered in eBRAP.

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

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

During eBRAP registration, the PI must request to be affiliated with his/her organization from the list of organizations already registered with eBRAP. If the PI's organization is not already registered with eBRAP, then the PI must invite an Authorized Organizational Representative (AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-proposal/pre-application submission deadline in order for the pre-proposal/pre-application to be submitted. However, before the full proposal/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-proposal/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-proposal/pre-application deadline, but the Business Official does not need to complete his/her registration for the pre-proposal/pre-application to be submitted. However, the Business Official's registration must be completed prior to the full proposal/application deadline to allow the Business Official to view/modify the full proposal/application files in eBRAP after Grants.gov submission.

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

The Grants.gov application package submitted to Grants.gov may be viewed in eBRAP until the end of the proposal/application verification period. After eBRAP has processed the Grants.gov proposal/application, PIs will receive an email informing them that the proposal/application components can now be viewed and modified in eBRAP. During the proposal/application verification period, the Grants.gov application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. See the BAA for specific full proposal/application submission and the proposal/application verification deadlines.

Specific information must be identical between the pre-proposal/pre-application and the full proposal/application for eBRAP to process a proposal/application. Mismatched information may delay the availability of the proposal/application during the proposal/application verification period. For the PI to view/modify files, the PI's name and email address in the eBRAP pre-proposal/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-proposal/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 the SF-424.

Grants.gov Registration: Refer to Appendix 3 for more information.

B. Submission Dates and Times

This BAA is continuously open for a 12-month period, from October 1, 2016 through September 30, 2017. **Pre-proposals/pre-applications are required** and may be submitted at any time throughout the 12-month period.

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

Registration through eBRAP (https://eBRAP.org) must be completed before a pre-proposal/pre-application can be submitted.

All pre-proposals/pre-applications must be submitted through eBRAP (https://eBRAP.org/).

2. Full Proposal/Application Submission through Grants.gov

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

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

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

If business is conducted with the Federal Government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management (SAM).

Detailed information, automated tools, and checklists are available at http://www.grants.gov/web/grants/applicants/organization-registration.html.

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

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

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

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

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

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

Tab 2 – Application Contacts: Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 Form). Depending on screen resolution, scrolling horizontally may be necessary to locate the box to Invite an AOR to register the performing and/or contracting organization. Click on "Add Organizations to this Pre-application." The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

If the organization's Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent.

Depending on the screen resolution, scrolling horizontally may be necessary to locate the box to Invite an AOR to register the performing organization (site at which PI will perform the proposed work) and contracting organization (organization submitting on behalf of the PI; corresponds to Block 5 on SF424), and click on "Add Organizations to this Pre-application." The organization(s) must either be selected from the eBRAP drop-down list or invited to allow the pre-proposal/pre-application to be submitted.

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

Note: The USAMRMC does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Unless otherwise noted, applicants should assign the role of each participant in accordance with the participant's respective involvement in the project.

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

If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable; however, 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 USAMRMC discourages inclusion of any employee of its review contractors in proposals/applications for funding. For FY17, the peer review contractor is CSRA, Inc. The programmatic review contractor is Leidos. Proposals/Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to Appendix 1 for additional information.

Tab 4 – Conflicts of Interest (COIs): 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 proposal/application (including those with whom the PI has a personal or professional relationship). Click on "Save."

Tab 5 – Required Files: Upload all documents as PDF as specified in the BAA. Documents should conform to the formatting guidelines outlined in Appendix 2. Click on "Upload."

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

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

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

Following completion of pre-proposal/pre-application submission, the status of the pre-proposal/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-proposal/pre-application in DRAFT status will not be forwarded for review.***

D. Content and Form of Proposal/Application Submission

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

A compatible version of Adobe Reader must be used to view, complete, and submit the Grants.gov application package. ***Grants.gov will reject an application package that is opened at any time by an individual with an incompatible version of Adobe Reader.*** Rejected proposals/applications must be resubmitted using a new Grants.gov application package and a supported version of Adobe Reader.

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

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

It is the applicant's responsibility to verify his/her Adobe Reader's compatibility with Grants.gov: http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html. A no-cost compatible version of Adobe Reader can be downloaded at http://www.grants.gov/web/grants/support.html. ***Resubmission of a proposal/application prior to the Grants.gov deadline must be coded as a "Changed/Corrected Application."***

The proposal/application consists of the following components:

1. eBRAP Log Number

During the pre-proposal/pre-application process, each submission will be assigned a unique log number by eBRAP in the following format: BA17XXXX. The corresponding Grants.gov application package must be submitted using this unique eBRAP log number.

- Enter the eBRAP log number acquired during the pre-proposal/pre-application process in Block 4.a. Federal Identifier Box of the SF424.

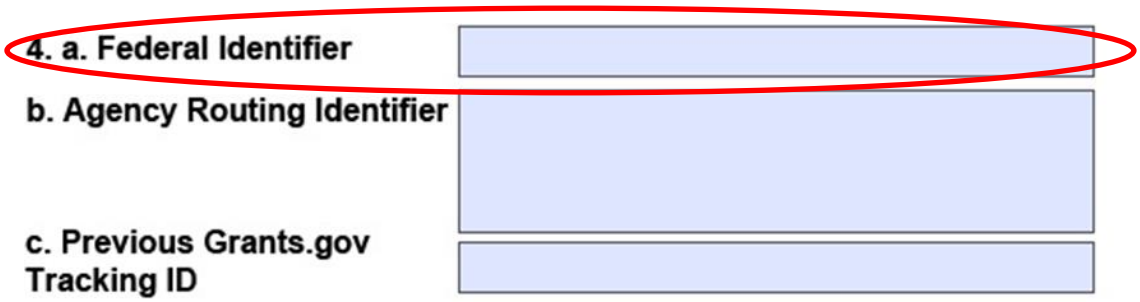
2. SF424 (R&R) Application for Federal Assistance Form

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in this 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 package must be resubmitted with the "Changed/Corrected Application" box selected.
- **Block 2 – Date Submitted.** Enter the date the proposal/application is submitted.
    - **Applicant Identifier.** Enter the submitting organization's Control Number, if applicable. If there is no Organization Control Number, leave this field blank.

- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.
- **Block 4.a. – Federal Identifier Box.** Enter the eBRAP log number acquired during the pre-proposal/pre-application process.

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



- **Block 4.b. – Agency Routing Identifier.** Not applicable.
- **Block 4.c. – Previous Grants.gov Tracking ID.** For changed/corrected proposals/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 U.S., enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select "New" for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-proposal/pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. The estimated end date should reflect the time needed to successfully complete the proposed project and not exceed 5 years. Actual start and end dates will be determined during negotiations if the proposal/application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the U.S., enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical

direction of the proposal/application. If outside the 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 and be consistent with the pre-proposal/pre-application budget.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option b. "NO, program is not covered by E.O.12372."
- **Block 17 – Complete Certification.** Select the "I agree" box to provide the required certifications and assurances**.**
- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL (SFLLL) to disclose lobbying activities pursuant to Title 31 United States Code Section 1352 (31 USC 1352).
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is automatically completed upon submission of the electronic application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.

3. Attachments Form

Grants.gov does not validate for the presence of attachments on this Attachments Form. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into the eBRAP to view, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the BAA guidelines. Discrepancies will be noted in both the email and in the Full Application 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 BAA. ***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.*** See "Verification of Grants.gov proposal/application in eBRAP" for additional details.

Each attachment in the Attachment 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. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted or for other guidance.

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

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

The following must be included as attachments to this form:

Attachment 1: Project Narrative: Named "ProjectNarrative.pdf." The Project Narrative is the main body of the proposal/application. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand on the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application/proposal. There is no form for this information. A detailed description of the research to be undertaken should be submitted. This should include the areas described in the BAA.

Submission of a Project Narrative that exceeds the page limit specified in the BAA will result in administrative rejection of the proposal/application.

Attachment 2: Supporting Documentation: Combine and attach as a **single PDF file named "Support.pdf."** Include only supporting documentation as indicated in the BAA. 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 proposal/application.***

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

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

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

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

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

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

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

SOW Format: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. ***The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching. The Government reserves the right to request a revised SOW format and/or additional information.***

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 USAMRMC regulatory review and approval, as shown below. Refer to Appendix 6 for additional information regarding regulatory review.
    - For studies involving human subjects, include a subtask that allows at least 2 to 3 months for regulatory review and approval by the USAMRMC Human Research Protection Office (HRPO); this does not include the additional time required for local Institutional Review Board (IRB) review and approval.
    - For animal studies, include a subtask that allows at least 2 to 3 months for regulatory review and approval by the USAMRMC Animal Care and Use Review Office (ACURO); this does not include the additional time required for local Institutional Animal Care and Use Committee (IACUC) review and approval.

Attachments 6-9: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the BAA (e.g., "Impact.pdf," "Transition.pdf," etc.).

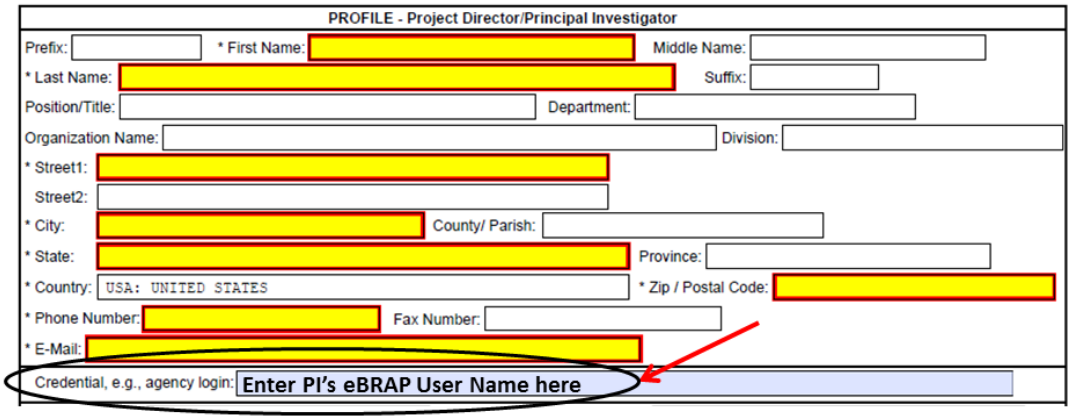
For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the BAA.

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

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

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

Figure 2. PI's eBRAP User Name



Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the "Funding Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. Use of this document is optional. The NIH Biographical Sketch may also be used. Each biographical sketch must be in PDF format prior to attachment. Note the page limitation specified in the BAA. Biographical Sketches should also be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

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

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

For all previous (award period of performance ending within the past 5 years), current, and pending research support, include the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting/Grants Officer, period of performance, level of funding, brief description of the project's goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

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

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

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

5. Research & Related Budget

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

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

Budget Regulations and Restrictions

The following must be utilized in developing the budget:

- **Administrative and Cost Principles.** Recipients are required to comply with the following, as applicable:
    - Federal Acquisition Regulation (FAR) Part 31
    - Defense FAR Supplement Part 231
    - Provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant and Agreement Regulations," Parts 26, 28, 34, 37, and 1125
    - 2 CFR Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the DoD interim implementation found at 2 CFR Part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR Part 200" (79 FR 76047, December 19, 2014).

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

- **Award Funding/Maximum Obligation:**
    - **Contract Awards:** Reference contract funding regulations in FAR 32.7 and DFARS 232.7.
    - **Assistance Agreement Awards:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Pre-Award Costs:** Pre-award costs may be allowable as follows:
    - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. An advanced agreement must be executed by the Contracting Officer prior to incurring any cost. Advanced Agreement Costs (Pre-Contract Costs) are referenced in FAR 31.205-32 and Advanced Agreements in 31.109.
    - **Assistance Agreement Awards:** An institution of higher education, hospital, or non-profit organization may, at its own risk and without the Federal Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the start date of the period of performance, if such costs (1) are necessary to conduct the project; and (2) would be allowable under the award, if awarded, without the Government's prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the costs. Government prior approval is required for any costs to be incurred more than 90 days before the start date of the period of performance. For-profit organizations must obtain the Grants Officer's approval prior to incurring any obligations and expenditures before the start date of the period of performance. Reference 2 CFR 200.458.

      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. Reference 32 CFR 34.15.

      The incurrence of pre-award costs imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. The Federal 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 in the approved timeframe or in any way adversely affect the conduct of the project.
- **Cost of Preparing Proposals/Applications:** The cost of preparing proposals/ applications in response to this BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals/applications may be an allowable expense included in the indirect/facilities and administrative cost as specified in the organization's applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the U.S. should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign

currency exchange rates for recipients performing research outside of the U.S. will be based on the official rate in effect at the time of submission.

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

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

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

For Collaborating Military Facilities: A proposal/application from an extramural organization that includes collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit a Collaborating DoD Military Facility Budget Form(s). Include any Military Facility's direct and indirect costs on this form. Also, include the Military Facility's total costs (direct and indirect) on the Subaward/Consortium/Contractual Costs line of the Research & Related Budget Form (Section F.5.). See Section II.D.8., Collaborating with DoD Military Facilities, for additional information.

Section A: Senior/Key Person

1. **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3.
2. **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
3. **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the

period of the award must be consistent with the applicable cost principles and organization's estimating procedures. ***For most Federal agencies, funding cannot be applied toward Federal salaries; therefore, these salaries should not be included in the requested budget.***

4. **Calendar, Academic, and Summer Months:** For each senior/key person, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.
5. **Requested Salary:** Enter the amount of salary requested for this budget period.
6. **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the proposal/application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).
7. **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
8. **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

1. **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
2. **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
3. **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.
4. **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most Federal agencies, funding cannot be applied toward Federal salaries; therefore, these salaries should not be included in the requested budget.***
5. **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the proposal/application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other Federally approved rate agreement, or other policy document).
6. **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description: Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per unit acquisition cost of (a) $5,000 or more per unit, or (b) the recipient's or subrecipients' capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If

equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

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

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

Section D: Travel: Travel costs may include:

1. Costs to attend **one** scientific/technical meeting per year: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be well justified and is subject to approval.
2. Costs for travel required for the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be well justified and is subject to approval.
3. The PI may be required to participate in an In-Progress Review (IPR). The PI should budget for an IPR yearly, lasting not more than two days and including up to two overnight stays, at the Contracting Officer's Representative's /Grants Officer's Representative's (COR/GOR) request. The invitation and format for the IPR will be provided by the COR/GOR at least (90) days prior to the meeting. The meetings will generally be held in the Fort Detrick, MD area but could occur elsewhere in the U.S.

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

Section F: Other Direct Costs

1. **Materials and Supplies:** Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment. The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing $5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

   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.

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.
5. **Subaward/Consortium/Contractual Costs:**
   - Include the total funds (direct and indirect costs) requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.
   - A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the R&R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form to show all direct and, if applicable, indirect costs. Also, include the Military Facility's total costs (direct and indirect) in the Subaward/ Consortium/Contractual Costs budget line of the Research and Related Budget Form (Section F.5.) See Section II.D.8., Collaborating with DoD Military Facilities below, for more information.
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.

For research involving human subjects, include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

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

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

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

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

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

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

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

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

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

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

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

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

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

If collaborating with a DoD Military Facility, do not complete this form; complete the Collaborating DoD Military Facility Budget Form. See Section II.D.8., Collaborating with DoD Military Facilities.

7. 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.

8. Collaborating with DoD Military Facilities

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

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

Direct Costs:

- **Salaries:** Include the positions/titles/ranks and levels of effort of all DoD civilian and military personnel expected to work on the extramural project, whether or not salaries/fringe benefits are proposed. Salaries/fringe benefits **may** be reimbursed, either directly by the Federal Government to the facility or through the extramural award to the facility, **but only under certain limited circumstances, which will be discussed during negotiations**. Applicant organizations can provide their personnel to

work on the project; those costs should not be included here but on the organization's Research and Related Budget Form (Sections A and B).

- **Travel:** Include costs to be incurred by DoD civilian and military personnel. However, **note that these costs cannot be reimbursed through the extramural award.** They can only be funded directly by the Federal Government to the facility. Some restrictions apply. Processes will be discussed during negotiations.
- **Consultants, Equipment, Materials, Supplies, Other, Etc.:** Include all anticipated direct costs. The Military Facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the Military Facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should be included on the applicant organization's Research & Related Budget Form and not included on this form.
- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DoD-established reimbursement rates (e.g., institutional review board fees, institutional animal care and use committee fees, etc.), the Military Facility's Resource Management (RM) office (or equivalent) must provide details of how the proposed rates/fees were determined. Rates/fees should be included in the Other Direct Costs line of the Research & Related Budget Form (Section F.8-10.).
- **Indirect Costs:** If an indirect cost rate is proposed, include documentation to support the rate (i.e., cost pool(s) and what items are included in each pool). The Military Facility should consult with its RM office (or equivalent) for assistance in determining a rate.
- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Subaward/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5.).

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

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

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRMC RM office is not able to "direct fund" the Military Facility, the funds may be placed

on the award and the contractor or recipient may provide award funds to the Military Facility. If known at the time of submission, the Military Facility, in conjunction with the applicant organization, should provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility and the associated costs, when the activities will take place, why "direct funding" is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc.

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

Technology Transfer: The Military Facility researcher(s) should also coordinate with his/her technology transfer office, when applicable. The facility may require that a cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) be executed between the facility and the contractor or recipient before work between the organization can begin or funds can be provided to the Military Facility. The CRADA (or other instrument) is not required at the time of proposal/application submission. A timeline for execution of the document will be established during negotiations.

E. Verification of Grants.gov proposal/application in eBRAP:

The ability to view and modify the Grants.gov proposal/application in eBRAP is contingent upon an organization, its Business Officials, and its PIs registering and being affiliated in eBRAP. eBRAP registration instructions are available in the user guide at https://ebrap.org/eBRAP/public/UserGuide.pdf.

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

The PI will have a period of 5 days from the date of proposal/application submission to Grants.gov, i.e., ***the verification period***, to complete this process. Once the verification period has ended, the PI will not be able to modify proposal/application components. ***If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.***

APPENDIX 1

QUALIFICATION AND ELIGIBILITY INFORMATION

A. Contractor/Recipient Qualification

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business with qualified organizations only. To be qualified, an organization must at least (1) have a satisfactory record of executing programs or activities under Federal procurement or assistance awards, if it is a prior recipient of such awards; (2) have a satisfactory record of integrity and business ethics; and (3) meet the qualifications and standards of the Federal Acquisition Regulations (FAR), Defense Federal Acquisition Regulations Supplement, the Department of Defense Grant and Agreement Regulations, and 2 CFR part 200, as applicable.

The U.S. Army Medical Research Acquisition Activity (USAMRAA) utilizes the Exclusions within the Performance Information functional area of the System for Award Management (SAM), formerly the Excluded Parties List System (EPLS), to identify individuals and organizations not qualified to receive Federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/.

B. Eligibility Information

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

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

General eligibility for investigators, organizations, and agencies:

- Eligible Investigators: Includes all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Note: Awards are made to organizations only, not individuals. Investigators must meet the specific BAA requirements.

- Eligible Organizations: Include 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 U.S.: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded intramural programs. Such agencies are required to explain how their proposals/ applications do not overlap with their intramural programs.

C. Conflict of Interest

1. Contract Awards:

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

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

2. Assistance Agreement Awards:

In accordance with 2 CFR 200.112, an organization must disclose in writing any potential conflict of interest to the Federal awarding agency or pass-through entity. All awards must be free of any COIs that could bias the research results. If selected for award, the recipient will be contacted by a Grants Officer to disclose any potential or actual COIs, along with a plan to manage them.

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

3. 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 FAR Part 3.104-4(c). If an applicant believes a post-employment restriction or COI may exist, the situation should be discussed with the USAMRMC legal staff (301-619-6598) prior to expending time and effort in preparation of a proposal/application.

APPENDIX 2

FORMATTING GUIDELINES

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

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

APPENDIX 3

GRANTS.GOV REQUIREMENTS

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

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

If business is conducted with the Federal Government on a continuing basis, it is likely that some of the 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 SAM (https://www.sam.gov) and receive confirmation of an "Active" status before submitting a proposal/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 proposal/ application submission.*** 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.***

Proposals/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" to the question "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 wherein the organization is located or by connecting to Form AC135 (http://www.nato.int/structur/AC/135/welcome.htm). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

4. Authorized Organizational Representative (AOR)

Each organization must have an AOR who is registered with Grants.gov (individual PIs do not register with Grants.gov). An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before submitting a proposal/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 proposal/application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the proposal/application is current, accurate, and complete.

APPENDIX 4

ADMINISTRATIVE INFORMATION AND REQUIREMENTS

A. Disclosure of Proprietary Information

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

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

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

B. Marking of Proprietary Information

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

C. Award Notices

Awards are made to organizations, not to individual Principal Investigators (PIs). The USAMRMC executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government will be determined by the Government prior to award, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, 31 USC[1] 6301-6308, which provides the legal criteria to select a procurement contract or an assistance agreement.

1. **A procurement contract** is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the United States Government (31 USC 6303).
2. **An assistance agreement (grant or cooperative agreement)** is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the U.S., instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative

[1] United States Code

agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. DoD staff may become directly involved in performing the research, managing the effort, and/or reviewing and providing approval before work can proceed.

After email notification that proposal/application review results can be found on the electronic Biomedical Research Application Portal (eBRAP), and if the proposal/application is selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

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

D. Inquiry Review

If a proposal/application is not recommended for funding, the organization or PI may submit an inquiry **within 15 business days** after the date on which the funding status notification email for that proposal/application 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 proposal/application. Inquiries in response to funding recommendations should be submitted to the USAMRAA Contracting or Grants Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether a factual or procedural error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Contracting or Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

E. Information Service

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

F. Freedom of Information Act Requests

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

When a FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the applicant will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A

valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the applicant will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

G. Information Release

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

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

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

"This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs (or other sponsoring agency), through the (insert program name) under Award No. (W81XWH-17-X-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 (http://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).
3. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules (http://www.nih.gov/)."
4. "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories (http://www.cdc.gov/biosafety/)."

Failure to comply may result in loss of funding.

H. Reporting Requirements for Awards

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

- Contractor Manpower Reporting (CMR)
    - CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing this data. A "nominal fee" is defined as a computation of an administrative assistant-equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.
    - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: https://cmra.army.mil/.
    - Reporting input will be for the labor executed during the period of performance during each Government fiscal year, which runs October 1 through September 30. While input may be reported any time during the fiscal year, all data shall be reported no later than October 31 of each calendar year.
    - Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil .
- Technical/Scientific:
    - Monthly, quarterly, and/or annual progress reports
    - Final progress report
    - In-progress reviews
    - Quad charts: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at https://cdmrp.org/Program_Announcements_and_Forms/ and completed for submission and application.

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

(ACURO) will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

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

I. Contracted Fundamental Research

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

J. Sharing of Application Information

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

K. Sharing of Data and Research Resources

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

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

- **Unique Data** 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#fin)
- **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 (such as PCR), methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf)

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

By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. The USAMRMC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Depending on the research project, the PI may be required to participate in the following, which will be specified in the award:

- **Traumatic Brain Injury (TBI):** For studies that will enroll TBI subjects, the DoD requires that the awardees make data available to the TBI research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System on a quarterly basis. The FITBIR Informatics System is a free resource to the TBI community designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and collaborate with others doing similar research. While use of the informatics system presents no direct cost to the user, a ***project estimation tool*** (https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp) is available to help estimate indirect cost and manpower needs associated with data submission.

  In order to facilitate FITBIR compliance, it is recommended that investigators contact the FITBIR Operations Center (FITBIR-ops@mail.nih.gov) during the proposal development phase to discuss submission requirements and potential Institutional Review Board (IRB) submission modifications.

  All reasonable efforts should be made to ensure that data elements are reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs). For the most current version of NINDS TBI CDEs, go to

http://www.commondataelements.ninds.nih.gov. Use of these TBI CDEs, as published, is required to facilitate data sharing and collaboration through the usage of standard definitions across studies. ***If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for its use.*** FITBIR Operations can provide assistance in mapping study variables to specific CDEs. If necessary, FITBIR Operations will work with researchers to create new, unique data elements when suitable data elements are not available in the FITBIR data dictionary.

Additional information, including the advantages of FITBIR use to the researcher, is detailed at the FITBIR website (http://fitbir.nih.gov/).

- **Clinical Trials:** If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (https://www.clinicaltrials.gov/).
- **Systems Biology:** If the project includes systems biology (SB) related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (https://sysbiocube-abcc.ncifcrf.gov/).

Application information may be shared with other Federal funding agencies (e.g., 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 web and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Updates on awards, including awardee information and published results are shared on the Defense Technical Information Center (DTIC).

L. Transfer of Award

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

Transfer of Assistance Agreement: An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

M. Change of Principal Investigator

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

N. Property/Equipment

Contracts: Reference FAR Part 45 and DFARS Part 245.

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

O. Title to Inventions and Patents

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

Contracts: FAR part 27 and DFARS part 227

Assistance Agreements: DoDGAR 34.25 and 2 CFR 200.315-316

P. J-1 Visa Waiver

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

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

Additional information on J-1 Visa Waivers can be located at the following Department of State website: https://travel.state.gov/content/visas/en.html.

APPENDIX 5

NATIONAL POLICY REQUIREMENTS

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

For regulatory requirements regarding the environment, and for use of animal and human subjects in research, refer to Appendix 6.

A. For all award types - Certification Regarding Lobbying Activities

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

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

(a) 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.

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

(c) 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. Contract Awards: Representations and Certifications:

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

C. Assistance Agreement Awards:

National policy requirements applicable to the Department of Defense (DoD) awards are listed in Appendices A and B to Part 22 of the DoD Grant and Agreement Regulations (DoDGAR) (32 CFR Subtitle A, Chapter 1, Subchapter C) (http://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol1/xml/CFR-2011-title32-vol1-subtitleA-chapI-subchapC.xml) and posted on USAMRAA's website at http://www.usamraa.army.mil/index.cfm?ID=12&Type=3.

1. Representations

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

a. 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:

(a) 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.

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

NOTE: If the applicant organization responds in the affirmative to either of the above representations, the organization is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the Government's

interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

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

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

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

2. The recipient must comply with the following requirements, incorporated herein by reference. The full text is available on http://www.usamraa.army.mil/:

(a) Requirements for Federal Funding Accountability and Transparency Act Implementation (2 CFR part 170): Appendix A to Part 170

(b) Financial Assistance Use of Universal Identifier and Central Contractor Registration (2 CFR 25): Appendix A to Part 25

(c) Trafficking Victims Protection Act

3. **The recipient must comply with the following requirements, as applicable. References titled "Effective November 2015: National Policy Requirements" are available on** http://www.usamraa.army.mil/.

- Nondiscrimination
- Campus Access for Military Recruiting and Reserve Officer Training Corps
- Research Involving Recombinant DNA Molecules
- Radioactive Materials
- Live Organisms (Human Subjects and Animals)
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Use of United States Flag Vessels
- Research Misconduct
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Whistleblower Protections
- Officials Not to Benefit
- Fly America Act
- Cargo Preference
- Environmental Standards
- Drug-Free Workplace
- Debarment and Suspension
- Trafficking in Persons

APPENDIX 6

REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

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

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 Data, Human Cadavers, and Animals

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

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

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

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

C. Research Involving Animal Use

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

Allow at least 2 to 3 months for regulatory review and approval processes for animal studies.

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

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

Research, development, test and evaluation (RDT&E), education, or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, dated 20 April 2012, available at http://mrmc.amedd.army.mil/index.cfm?pageid=research_%20protections.overview. The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. **HRPO must review the use of post-mortem specimens for compliance with the Army Cadaver Use Policy.** Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcomusamrmc.other.hrpo@mail.mil.

E. Research Involving Use of Human Anatomical Substances and/or Human Subjects Data

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

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (https://ebrap.org/eBRAP/public/Program.htm). This information is a guide only; it is not intended to be a source for human 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 (FDA) as appropriate.

HRPO review and determination is required for secondary use of existing human anatomical substances (biospecimens) for research. HRPO review and determinations for biospecimen research are based upon the nature of the research, the source of the tissue, use and/or disclosure of identifiable health information, privacy and confidentiality protections, and whether informed consent/authorization of subjects should be required, among other factors. The HRPO requires a copy of the consent form used to collect the specimens/data to determine whether the proposed research is consistent with any specific terms under which the specimens were collected. The HRPO will verify all required institutional and host nation approvals are completed as part of the review.

F. Research Involving the Secondary Use of Data/Specimens

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

G. Research Involving Human Subjects

For in-depth information and to access HRPO Protocol Submission Form, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (https://ebrap.org/eBRAP/public/Program.htm). This information is a guide only; it is not intended to be a source for human 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 FDA as appropriate.

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

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

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already-approved protocol must be

approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the "Information for Investigators" found at http://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 or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

1. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.
2. **Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.
3. **Informed Consent Form:** The following must appear in the consent form:
   - A statement that the DoD is providing funding for the study.
   - A statement that representatives of the DoD are authorized to review research records.
   - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.
4. **Intent to Benefit:** The requirements of Title 10 United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

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

primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

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

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

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

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

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

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

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

location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

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

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

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

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

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

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

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

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

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

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

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

H. Clinical Trial Registry

PIs are required to register clinical trials individually on https://www.clinicaltrials.gov/ using a Secondary Protocol ID number designation of "CDMRP-CDMRP Log Number" (e.g., CDMRP-BA17####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-CDMRP Log Number-A, B, C, etc." (e.g., CDMRP-BA17####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (https://clinicaltrials.gov/ct2/manage-recs/fdaaa) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

I. 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 https://auth.osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines_PRN_1-sided.pdf.

APPENDIX 7

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
APAN	Assistance/Procurement Advisory Notice
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
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
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
DoDI	Department of Defense Instruction
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
eBRAP	electronic Biomedical Research Application Portal
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ET	Eastern Time
F&A	Facilities and Administrative
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency TBI Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
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
MB	Megabyte
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health
OHRP	Office for Human Research Protection
OMB	Office of Management and Budget
ORP	Office of Research Protections
PARC	Principal Assistant Responsible for Contracting
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SB	Systems Biology
SFLLL	Standard Form LLL
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio