General Submission Instructions

Broad Agency Announcement for Medical Research

Fiscal Year 2023 – Fiscal Year 2027

Department of Defense

U.S. Army Medical Research and Development Command

Table of Contents

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 (BAA) for specific instructions.

B. Current Funding Opportunity Announcement

The Fiscal Year 2023 – Fiscal Year 2027 (FY23 – FY27) U.S. Army Medical Research and Development Command's (USAMRDC) BAA can be found by searching Grants.gov (https://www.grants.gov/) using the Funding Opportunity Number **HT942523SBAA1** or the Assistance Listing 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/Grants/Agreements Officers are the only individuals authorized to obligate funds and bind the federal government for awards under this BAA.

C. Receiving Emails from eBRAP and Grants.gov

To help ensure that all email correspondence is delivered correctly and is not treated as spam, keep your email address up to date in eBRAP and Grants.gov and place the following domains into your safelist: army.mil, us.army.mil, health.mil, *.mail.mil, eBRAP.org, and Grants.gov. Also use the same email address when submitting both the pre-proposal/pre-application to eBRAP and the full proposal/application to Grants.gov.

The applicant is responsible for using the latest version of the full proposal/application package (hereinafter, submission package). It is incumbent upon the applicant to check for published updates to the funding opportunity and the submission package prior to submission.

Proposals/applications submitted without the required components of the full submission package may be rejected. Applicants are encouraged to sign up to receive notifications of any changes to the funding opportunity (https://www.grants.gov/) through either **(1)** the "Send me change notification emails" link on the Synopsis page for the BAA or **(2)** by responding to the Grants.gov prompt *when first downloading the Grants.gov submission package*.

D. Agency Contacts

1. **eBRAP 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 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. The eBRAP Help Desk will not provide Grants.gov submission assistance.

Phone: 301-682-5507 (Monday through Friday, 8:00 a.m. to 5:00 p.m.)

Email: help@ebrap.org

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

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

Email: support@grants.gov

II. REGISTRATION AND SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-proposal/pre-application submission through eBRAP (https://eBRAP.org/) and (2) full proposal/application submission through a Grants.gov Workspace. 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 https://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 III.A.5, Research & Related Budget and Section III.A.8, Suggested DOD Collaborating Military Facility Budget Format.

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

A. eBRAP Registration

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-proposals/pre-applications, view and verify extramural full proposals/applications submitted to Grants.gov, receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance.

All PIs must register in eBRAP to submit a pre-proposal/pre-application.

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

During eBRAP registration, the PI must request to be affiliated with their organization from the list of organizations already registered with eBRAP. If the PI's organization is not already registered with eBRAP, 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, the organization's eBRAP registration must be completed before the full proposal/application submission deadline to allow for processing, viewing, and modifying select components of the full proposal/application package.***

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

Applicants should ensure that their name and email address are the same as the name and email address on the Standard Form 424 Research and Related (SF424 Research & Related) Form of the Grants.gov application package submitted through Grants.gov Workspace.

PIs are encouraged to utilize an Open Researcher and Contributor ID (ORCID) identifier and enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP. An ORCID will be required if an application is subsequently recommended for funding.

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

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

All pre-proposal/pre-application components must be submitted through eBRAP (https://eBRAP.org/) by the deadline specified in the BAA. Click on "Submit" and "Confirm Submission" to complete the pre-proposal/pre-application submission.

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. The Business Official's registration must be completed prior to the full proposal/application deadline to allow the Business Official to view, modify, and verify the full proposal/application in eBRAP after 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) and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited to allow submission of the pre-proposal/pre-application.

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

Tab 1 – Proposal/Application Information: Enter the proposal/application information as described in eBRAP before continuing the pre-proposal/pre-application. Submission of proposal/application information includes assignment of primary and secondary research classification codes, which can be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection. Click on "Save."

Tab 2 – Proposal/Application Contacts: Enter contact information for the PI. Enter the name of the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of SF424 in the Grants.gov package). Depending on screen resolution, scrolling horizontally may be necessary to locate the box to "Invite an AOR" to register the performing and/or contracting organizations. Click on "Add Organizations to this Pre-application." The Business Official must be either selected from the eBRAP list or invited to allow the pre-proposal/pre-application to be submitted. The Business Official must be either selected from the eBRAP list or invited in order for the pre-proposal/pre- application to be submitted.

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

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 USAMRDC does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Unless otherwise noted in the BAA, 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) those military facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

Tab 4 – Conflict of Interest (COI): 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 – Pre-Proposal/Pre-Application Files: Upload all documents as PDF as specified in the BAA. Documents should conform to the formatting guidelines outlined in Appendix 4. Click on "Upload."

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

Tab 6 – Submit Pre-Proposal/Pre-Application: Enter 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 remain 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. ***A pre-proposal/ pre-application in DRAFT status will not be forwarded for review.***

III. CONTENT AND FORM OF PROPOSAL/APPLICATION SUBMISSION FOR RESEARCH PROPOSALS/APPLICATIONS

Grants.gov (https://grants.gov) is a federal system required to be utilized by agencies to receive and process extramural grant applications. Each proposal/application submission must include the completed full proposal/application package for the BAA. The full proposal/application package is submitted by the AOR through Grants.gov (https://www.grants.gov/) for extramural organizations.

Grants.gov applicants must apply online using Workspace, a shared, online environment where members of a grant team (investigators and Business Officials) may simultaneously access and edit different webforms within a proposal/application. Applicants must create a Workspace, invite grant team members to join the Workspace, complete the required forms, and submit their proposal/application Workspace package.

To apply through Grants.gov, an organization must first complete the Grants.gov registration process. ***Allow up to 8 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. 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.

Detailed information, automated tools, and checklists are available at https://grants.gov/applicants/applicant-registration/.

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

1. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an Entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting a proposal/application through Grants.gov.

AORs with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see below).

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 (E-Biz) 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 deadline.*** An organization can register in SAM online at https://www.sam.gov/SAM/. 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 several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination to direct the federal award to a qualified applicant.

Additional information and step-by-step registration directions are detailed in the SAM User Guide and other GSA training materials in the Help area at https://www.sam.gov/SAM. Proposals/applications will be rejected by Grants.gov if (1) the organization's Entity registration in SAM is not active or (2) during the SAM registration process, the organization did not answer "Yes" when asked, "Do you want to be eligible for grants and other federal assistance?"

2. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE codes. CAGE codes will be assigned to registrants as their SAM registration advances through the validation process.

Foreign registrants in SAM must be assigned a North Atlantic Treaty Organization (NATO) CAGE code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by visiting the website (https://cage.dla.mil/Home/UsageAgree). On average, CAGE code or NCAGE code validation in SAM occurs within 3 business days after the TIN is validated.

3. Authorized Organizational Representative

Each organization must have an AOR who is registered with Grants.gov (individual PIs do not register with Grants.gov). An AOR must be a member of the Grants.gov Workspace grant team as the Business Official authorized to submit the completed Workspace proposal/application package. An organization's E-Biz POC in Grants.gov must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before proposal/application submission, the AOR must be registered to submit on behalf of the organization at Grants.gov (https://apply07.grants.gov/apply/register.faces).

An AOR must first register with the Grants.gov credential provider at https://apply07.grants.gov/apply/register.faces to obtain a username and password. Once an AOR has completed the Grants.gov registration process, Grants.gov will notify the E-Biz POC of the registration. The E-Biz POC will then log in to Grants.gov and assign and authorize the appropriate roles, which may include the AOR role, thereby giving the AOR permission to complete and submit proposals/applications on behalf of the organization. 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 their knowledge that all information provided in the proposal/application is current, accurate, and complete.

For proposals/applications submitted through Grants.gov, the name of the AOR submitting the proposal/application is inserted into the application's signature line, serving as the electronic signature.

Individuals who make legally binding commitments on behalf of an organization must be authorized as AORs by the E-Biz POC. This step, often overlooked by applicants, is crucial for valid and timely submissions.

4. Grants.gov Workspace

Applicants must create a Grants.gov Workspace, which allows the proposal/application components to be completed online and routed through the applicant organization for review prior to submission. Once the Workspace has been created, participants (grant team members) can be added, and the required forms can be completed and reviewed before submitting.

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

Applicants who prepare the proposal/application outside Workspace must download the individual PDF forms from Grants.gov, complete and save the forms, and upload them to the Workspace. A compatible and identical version of Adobe Reader must be used to view, complete, and submit a proposal/application package consisting of PDF forms if more than one person accesses the proposal/application package. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. ***Grants.gov will reject a submission 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 submission package and a supported version of Adobe Reader prior to the proposal/application submission deadline. It is the applicant's responsibility to verify their Adobe Reader's compatibility with Grants.gov: https://grants.gov/applicants/adobe-software-compatibility. A no-cost compatible version of Adobe Reader can be downloaded at https://get.adobe.com/reader/otherversions/. All contributors to the proposal/application must use matching compatible versions of Adobe software when editing and preparing proposal/ application components outside the Workspace. The use of different software versions will result in corruption of the submitted file.

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

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

The proposal/application submission deadline and the end of the proposal/application verification period in eBRAP are stated on the first page of the BAA. See Section III.C, Applicant Verification of Grants.gov Submission in eBRAP, for additional details.

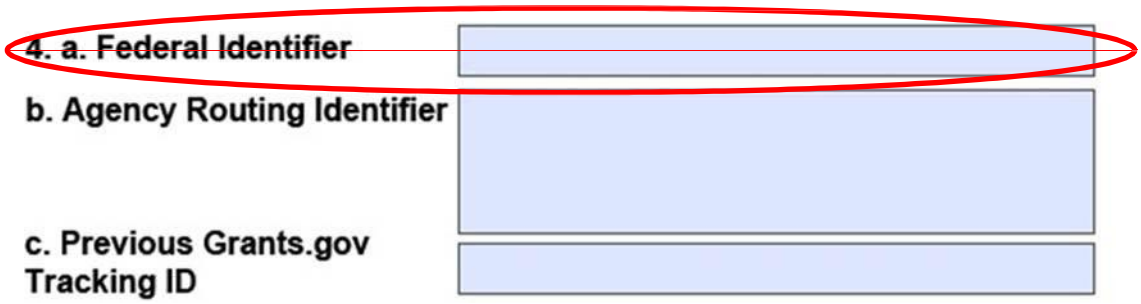
A. Grants.gov Submission Package Components

1. SF424 (Research & Related), Application for Federal Assistance Form

All appropriate information must be entered into this form to allow for auto-population of subsequent forms in this Grants.gov submission package.

- **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 submission package must be resubmitted with the "Changed/Corrected Application" box selected.
- **Block 2 – Date Submitted.** Enter the date the proposal/application is submitted.
- **Applicant Identifier.** Enter the submitting organization's Control Number, if applicable. If there is no Organization Control Number, leave this field blank.
- **Block 3 – Date Received by State and State Application Identifier. Not** applicable.
- **Block 4a – Federal Identifier Box.** Enter the eBRAP log number assigned during pre-proposal/pre-application submission.

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



- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/corrected proposals/ applications, enter the Grants.gov tracking number for the original proposal/application.
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. "Person to be contacted on matters involving this application" is the Business Official.
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue Service. If applying from an organization outside the United States, enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select "New" for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-proposal/pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the proposal/ application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the 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.

- **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. ***By checking "I Agree" on block 17 of the SF424 (R&R) the applicant agrees to abide by the following statement: "By signing this proposal/application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal/application is current, accurate and complete; (b) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties." (U.S. Code, Title 18, Section 1001 [18 USC 1001]). Checking "I agree" confirms compliance with the National Policy Requirements, Appendix 5.***

- **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 31 USC 1352.

- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is automatically completed upon submission of the Grants.gov submission package.

- **Block 20 – Pre-Proposal/Pre-Application.** Not applicable.

- **Block 21 – Cover Letter Attachment.** Not applicable.

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

2. Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form. Following retrieval and processing of the Grants.gov proposal/application, eBRAP will notify the organizational representatives and PI by email to log into the eBRAP to view, modify, and verify the Grants.gov proposal/application submission. eBRAP will validate retrieved files against the specific BAA requirements, and discrepancies will be noted in both the email and in the Full Application Files tab. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA. See Section III.C, Applicant Verification of Grants.gov Submission 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 4. For all attachments, ensure that the file names are consistent with the guidance listed in the BAA and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire submission package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted.

For specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form, refer to the 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: Attach as a PDF 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) used to describe the project. Inclusion of URLs (uniform resource locators; web addresses) 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 proposal/application.

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 proposal/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 provided fair and thorough reviews. Letters of support not requested in the BAA, such as those from members of Congress, will be removed from the proposal/application package.

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

The data management plan should include but is not limited to:

(1) The types of data, software, and other materials to be produced.

(2) How the data will be acquired.

(3) Time and location of data acquisition, if scientifically pertinent.

(4) How the data will be processed.

(5) The file formats and the naming conventions that will be used.

(6) A description of the quality assurance and quality control measures during collection, analysis, and processing.

(7) A description of dataset origin when existing data resources are used.

(8) A description of the standards to be used for data and metadata format and content.

(9) Appropriate timeframe for preservation.

(10) The plan may consider the balance between the relative value of data preservation and other factors such as the associated cost and administrative burden. The plan will provide a justification for such decisions.

(11) ***Include a statement that the data cannot be made available to the public when there are national security or controlled unclassified information concerns (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoD Directive 5230.09.")***.

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.

Attachment 3: Technical Abstract: Attach as a PDF file named "TechAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.health.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. Do not include proprietary or confidential information.

Attachment 4: Lay Abstract: Attach as a PDF file named "LayAbs.pdf". Abstracts of all funded research projects will be posted on the CDMRP website at https://cdmrp.health.mil. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract***. 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. Do not include proprietary or confidential information.

Attachment 5: Statement of Work (SOW): Attach as a PDF file named "SOW.pdf". The SOW outlines and establishes the performance expectations and milestones for which USAMRDC may provide funding. 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: PIs are strongly encouraged to use the suggested SOW format stated in the BAA. Templates for SOW formats are available on the eBRAP "Funding Opportunities & Forms" page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching.

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 the proposal/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, human data 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 USAMRDC regulatory review and approval, as shown below. Refer to Appendix 1 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 USAMRDC Office of Human Research Oversight (OHRO); 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 USAMRDC 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 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the BAA (e.g., "Impact.pdf," "Transition.pdf").

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

3. Research & Related Personal Data

This form will be used by the Department of Defense (DOD) as the source of demographic information, such as sex, race, ethnicity, and disability information, for the Project Director (PD)/PI and all other persons identified as Co-PD(s)/Co-PI(s).

Each proposal/application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the "Next Person" button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to reviewers. Applicants who do not wish to provide some or all of the information should check or select the "Do not wish to provide" option.

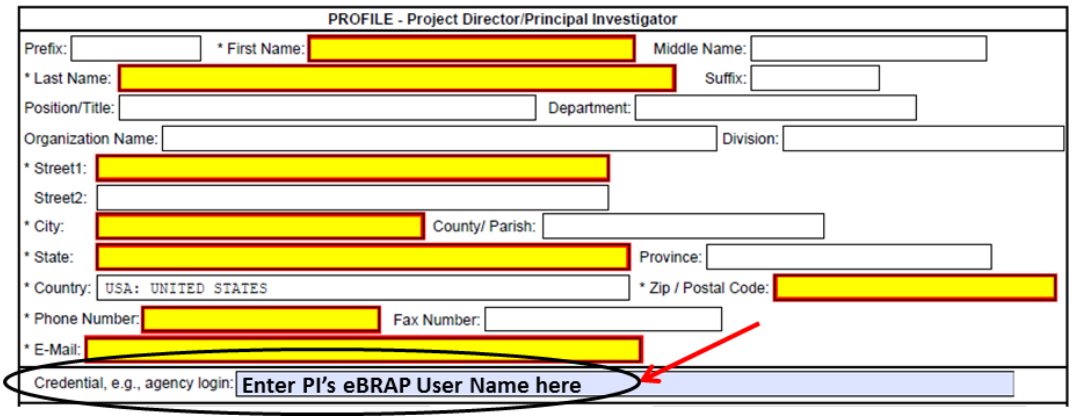
4. Research & Related Senior/Key Person Profile (Expanded)

The Degree Type and Degree Year fields on the Research & Related Senior/Key Person Profile (Expanded) form will be used by DOD as the source for career information. In addition to the required fields on the form, applicants must complete these two fields for all individuals that are identified as having the project role of PD/PI or Co-PD/Co-PI on the form. Additional senior/ key persons can be added by selecting the "Next Person" button.

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

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

Figure 2. PI's eBRAP User Name



- **Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf" where "LastName" is the last name of the PI or Senior/Key Person.

  Biographical sketches must conform to the federal wide Biographical Sketch Common Form. Applicants may use the instructions provided below, or may use a pdf form created in SciENcv for the NIH or the U.S. National Science Foundation (NSF).

  The following provides instructions for submitting the biographical sketch for each individual identified as a Senior/Key Person on the proposal. These instructions serve as the CDMRP's implementation of the Biographical Sketch Common Form developed by the National Science and Technology Council's Subcommittee on Research Security. A complete list of terms and definitions is available in the National Security Presidential Memo – 33 (NSPM-33) Implementation Guidance.

  Consistent with NSPM-33, individuals are required to disclose contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if an individual receives direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government-sponsored or affiliated activities. In accordance with 42 USC 19232, the Malign Foreign Talent Recruitment Program Prohibition Statute, individuals are prohibited from being a party in a malign foreign talent recruitment program.

  The table entitled NSPM-33 Implementation Guidance Pre- and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending (Other) Support provides helpful reference information regarding pre-award and post-award disclosures. The table includes the types of activities to be reported, where such activities must be reported in the proposal, as well as when updates are required in the proposal and award lifecycle. A final column identifies activities that are not required to be reported.

Provide only the information requested below in the order it is listed. All elements are required unless otherwise noted. There is no page or character limit to this section of the proposal.

(1) Identifying Information

- **Name:** Enter the name of the Senior/Key person (Last name, First name, Middle name, including any applicable suffix).

- **ORCID of the Senior/Key Person (optional):** Enter the ORCID of the Senior/Key person. The ORCID is a unique, open digital identifier that distinguishes the individual from every other researcher with the same or a similar name.

- **Position Title:** Enter the current position title of the Senior/Key person.

(2) Organization and Location

- **Name:** Enter the name of the primary organization of the Senior/Key person.

- **Location:** Enter the City, State/Province, and Country where the primary organization is located. If the State/Province is not applicable, enter N/A.

(3) Professional Preparation

Provide a list of the Senior/Key person's professional preparation (e.g., education and training), listed in reverse chronological order by start date. Include all postdoctoral and fellowship training, as applicable, listing each separately. Also include the baccalaureate degree or other initial professional education.

- For each entry, provide:

  - Name of the organization

  - Location of the organization: Enter the City, State/Province, and Country where the organization is located. If the State/Province is not applicable, enter N/A.

  - Degree received (if applicable)

  - Start date of the degree or fellowship program

  - Month and year the degree was received (or expected receipt date)

  - Field of study

(4) Appointments and Positions

- A list, in reverse chronological order by start date, of all the individual's academic, professional, or institutional appointments and positions, beginning with the current appointment (including the associated organization and location). Appointments and positions include any titled academic, professional, or institutional position whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).

- Senior/Key persons must only identify all domestic and foreign professional appointments and positions outside of the primary organization for a period up to three years from the date the applicant submits the application to the CDMRP for funding consideration.

- For each entry provide:

  - Start date: YYYY
  - End date: YYYY
  - Appointment or position title
  - Name of organization
  - Department (if applicable)
  - Location of organization: City, State/Province, Country

(5) Products

Provide a list of products that demonstrate the individual's qualifications to carry out the project as proposed. It is up to the individual to determine how to best organize this listing to demonstrate their ability to carry out the project. Acceptable products must be citable and accessible, including but not limited to:

- Publications, conference papers and presentations

- Website(s) or other internet site(s)

- Technologies or techniques

- Inventions, patents, patent applications and/or licenses

- Other products, such as data, databases, or datasets, physical collections, audio or video products, software, models, educational aids or curricula, instruments or equipment, research material, interventions (e.g., clinical or educational), or new business creation

Each product must include full citation information including:

- Names of authors
- Product title
- Date of publication or release
- Website URL
- Other persistent identifier (if available)
- Other relevant citation information (e.g., in the case of publications, title of enclosing work such as journal or book, volume, issue, pages)

If any of the items specified above is not applicable, enter N/A.

Senior/Key personnel who wish to include publications in the products section of the Biographical Sketch that include multiple authors may, at their discretion, choose to list one or more of the authors and then "et al" in lieu of including the complete listing of authors' names.

(6) Certification

Each Senior/Key person is required to complete the following certifications regarding the information provided in their Biographical Sketch:

- I certify that the information provided is current, accurate, and complete. This includes but is not limited to information related to domestic and foreign appointments and positions.
- I also certify that, at the time of submission, I am not a party in a malign foreign talent recruitment program.

Misrepresentations and/or omissions may be subject to prosecution and liability pursuant to, but not limited to, 18 USC §§ 287, 1001, 1031 and 31 USC §§ 3729-3733 and 3802.

Signature and Date: To be acceptable, the date of the signature must be within the past 12 months from when the document is submitted.

- **Current/Pending Support:** This file must be titled "Support_LastName.pdf" where "LastName" is the last name of the PI or Senior/Key Person.

  Current and pending support documentation must conform to the federal wide format. Applicants may use the instructions provided below, or may use a pdf form created in SciENcv for NIH or NSF.

The following provides instructions for submitting current and pending (other) support information for each individual identified as a Senior/Key person on a CDMRP application. These instructions serve as the CDMRP's implementation of the Current and Pending (Other) Support Common Form. A complete list of terms and definitions is available in the NSPM-33 Implementation Guidance.

A separate submission must be provided for each proposal and active project, as well as in-kind contributions using the instructions and format specified below.

Consulting activities must be disclosed under the Proposals/Active Projects section of the form when any of the following scenarios apply:

- The consulting activity will require the Senior/Key person to perform research as part of the consulting activity.
- The consulting activity does not involve performing research, but is related to the Senior/Key person's research portfolio and may have the ability to impact funding, alter time or effort commitments, or otherwise impact scientific integrity.
- The consulting entity has provided a contract that requires the Senior/Key person to conceal or withhold confidential financial or other ties between the Senior/Key person and the entity, irrespective of the duration of the engagement.

Consistent with NSPM-33, individuals are required to disclose contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if individuals receive direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government sponsored or affiliated activities. In accordance with 42 USC 19232, the Malign Foreign Talent Recruitment Program Prohibition Statute, individuals are prohibited from being a party in a malign foreign talent recruitment program.

The table entitled NSPM-33 Implementation Guidance Pre- and Post-award Disclosures Relating to the Biographical Sketch and Current and Pending (Other) Support provides helpful reference information regarding pre-award and post-award disclosures. The table includes the types of activities to be reported, where such activities must be reported in the application, as well as when updates are required in the application and award lifecycle. A final column identifies activities that are not required to be reported.

Note that there is no page limitation for this section of the application, though some fields have character limitations for consistency and equity. Provide only the information requested in the order it is listed. All elements are required unless otherwise noted.

(1) Identifying Information

- **Name:** Enter the name of the Senior/Key person (Last name, First name, Middle name, including any applicable suffix).

- **ORCID of the Senior/Key Person (optional):** Enter the ORCID of the Senior/Key person. The ORCID is a unique, open digital identifier that distinguishes the individual from every other researcher with the same or a similar name.

- **Position Title:** Enter the current position title of the Senior/Key person.

(2) Organization and Location

- **Name:** Enter the name of the primary organization of the Senior/Key person.

- **Location:** Enter the City, State/Province, and Country where the primary organization is located. If the State/Province is not applicable, enter N/A.

(3) Proposals/Active Projects

In this section, disclose ALL proposals and active projects in accordance with the definitions for current and pending (other) support.

- **Title:** Enter the title of each project/active proposal being reported.

- **Status of Support:** Select the appropriate status type as defined below:

  - Current: All active projects, or projects with ongoing obligations, from whatever source irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

  - Pending: Any proposal that is being considered for funding from a potential funding organization (including this proposal) irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

- **Proposal/Active Award Number (if available):** Enter the applicable proposal/active award number for each proposal and/or award, if available.

- **Source of Support:** Identify the entity for each proposal and/or active project that is providing the support. Include all Federal, State, Tribal, territorial, local, foreign, public or private foundations, non-profit organizations, industrial or other commercial organizations, or internal funds allocated toward specific projects.

- **Primary Place of Performance:** Identify the primary location where the proposal and/or active project is being executed. Enter the City,

State/Province, and Country where the organization is located. If the State/Province is not applicable, enter N/A.

- **Proposal/Active Project Start Date:** Indicate the start date (MM/YYYY) of the project, as proposed/awarded.

- **Proposal/Active Project End Date:** Indicate the end date (MM/YYYY) of the project, as proposed/awarded.

- **Total Anticipated Proposal/Project Amount:** Enter the total award amount for the entire period of performance, inclusive of indirect costs, rounded to the nearest dollar. If the dollar value is not readily ascertainable, a reasonable estimate should be provided. If the support is in a foreign country's currency, convert to U.S. dollars at time of submission.

- **Person-Month(s) (or Partial Person-Months) Per Year Devoted to the Proposal/Active Project:** Enter how much time the individual anticipates is necessary to complete the scope of work on the proposal and/or active project. Enter the number of person-months (even if unsalaried) for the current budget period and enter the proposed person-months for each subsequent budget period. If the time commitment is not readily ascertainable, a reasonable estimate should be provided.

- **Overall Objectives:** Provide a brief statement of the overall objectives of the proposal/active project. This field is limited to 1500 characters.

- **Statement of Potential Overlap:** Enter a description of the potential overlap with any pending proposal or active foreign or domestic project and this proposal in terms of scope, budget, or person-months planned or devoted to the project by the individual. If there is no potential overlap, enter "none" in this field.

(4) In-Kind Contributions

In this section, disclose ALL in-kind contributions with an estimated dollar value of $5000 or more and that require a commitment of the individual's time. An in-kind contribution is a non-cash contribution provided by an external entity that directly supports the individuals' research and development efforts. An in-kind contribution may include but is not limited to: real property; laboratory space; equipment; data or data sets; supplies; other expendable property; goods and services; employee or student resources. In-kind contributions with an estimated value of less than $5000 need not be reported.

- **Status of Support:** Select the appropriate status type as defined below:

  - Current: All in-kind contributions obligated from whatever source irrespective of whether such support is provided through the proposing

organization or is provided directly to the individual.

- Pending: All in-kind contributions currently under consideration from potential funding organizations irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

- **Receipt (or Anticipated Receipt) Date of In-Kind Contribution:** Enter the receipt date (or anticipated receipt date) of the in-kind contribution.

- **Source of Support:** Identify the entity (entities) that is providing the in-kind contribution. Include, for example, Federal, State, Tribal, territorial, local, foreign, public or private foundations, non-profit organizations, industrial or other commercial organizations, or internal funds allocated toward specific projects.

- **Summary of In-Kind Contribution(s):** Enter a summary of the in-kind contribution not intended for use on the proposal/active project.

- **Person-Month(s) (or Partial Person-Months) Per Year Devoted to the In-Kind Contribution:** Enter how much time the individual anticipates is necessary to complete the scope of work associated with use of the in-kind contribution. Enter the number of person-months (even if unsalaried) for the current budget period and enter the proposed person-months for each subsequent budget period. If there is no associated time commitment, the in-kind contribution need not be reported.

- **U.S. Dollar Value of In-Kind Contribution:** Enter the U.S. dollar value of the in-kind contribution with an estimated value of $5000 or more. If the dollar value is not readily ascertainable, a reasonable estimate should be provided. If the support is in a foreign country's currency, convert to U.S. dollars at time of submission rounded to the nearest dollar.

- **Overall Objectives:** Provide a brief statement of the overall objectives of the in-kind contribution(s). This field is limited to 1500 characters.

- **Statement of Potential Overlap:** Enter a description of the potential overlap with any current or pending foreign or domestic in-kind contribution and this proposal in terms of scope, budget, or person-months planned or devoted to the project by the individual. If there is no overlap, enter "none" in the field.

(5) Certification

Each Senior/Key person is required to complete the following certifications regarding the information provided in their Current and Pending (Other) Support:

- I certify that the information provided is current, accurate and complete. This includes, but is not limited to, information related to current, pending, and other support (both foreign and domestic) as defined in 42 USC §6605.

- I also certify that, at the time of submission, I am not a party in a malign foreign talent recruitment program.

Misrepresentations and/or omissions may be subject to prosecution and liability pursuant to, but not limited to, 18 USC §§287, 1001, 1031 and 31 USC §§3729-3733 and 3802.

Signature and Date: To be acceptable, the date of the signature must be within the past 12 months from when the document is submitted.

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

- **Key Personnel 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 Current/Pending Support" listed above.

Note: Other support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value and/or where they are based. This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.).

New Requirement: Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PIs (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;

- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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. For limits on funding amounts, types of costs, and period of performance, refer to the BAA. The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. ***The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.*** At the time of proposal/application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate, and complete.

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

No budget will be approved by the government exceeding the cost limit stated in the specific program announcement or using an indirect rate exceeding the organization's negotiated rate.

Budget Regulations and Restrictions:

The following must be utilized in developing the budget:

- **Administrative and Cost Principles:** Awardees are required to comply with the following, as applicable:
    - Federal Acquisition Regulation (FAR) Part 31
    - Defense Federal Acquisition Regulation Supplement Part (DFARS) 231
    - Provisions of Title 32 of the Code of Federal Regulations, Chapter I, Subchapter C. "DoD Grant and Agreement Regulations," Parts 26, 28, 34, 37 (32 CFR, Chapter 1, Subchapter C, Parts 26, 28, 34, 37, and 2 CFR Part 1125, "Nonprocurement Debarment And Suspension"
    - 2 CFR Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," implemented by Chapter XI of 2 CFR
- **Award Funding/Maximum Obligation:**
    - Contract Awards: Reference contract funding regulations in FAR Subpart 32.7 and DFARS Subpart 232.7
    - Assistance Agreement Awards: Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/F&A 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. Advance Agreement Costs (Pre-Contract Costs) are referenced in FAR 31.205-32 and Advance Agreements in FAR 31.109.

- **Assistance Agreement Awards:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the 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. If specific expenditures would otherwise require prior approval, the awardee 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 Contracting/Grants/Agreements Officer's approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award.

  The incurrence of pre-award costs in anticipation of an award imposes no obligation on the government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The government expects the awardee to be fully aware that pre-award costs may result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives within the approved 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 the BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals/applications may be an allowable cost that can be included in the indirect/F&A costs as specified in the organization's applicable cost principles.

- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for recipients performing research outside of the United States will be determined at the time of proposal/application submission.

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

Budget Instructions: Complete the Research & Related Budget following the instructions below. Begin by entering the organizational UEI number, Budget Type, Name of Organization,

and anticipated start and end dates. ***Ensure that the UEI number is entered accurately or Grants.gov will reject the proposal/application.***

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, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) must submit a DOD Military Budget as instructed in Section III.A.8, Suggested Intragovernmental/Intramural Budget below. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs.

Foreign Collaboration Justification: Applications/proposals that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:

The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location or population not generally available to investigators based in the U.S. (or which would require significant effort or time to duplicate) or would potentially significantly advance the health sciences in the United States.

The foreign organization, individual(s) employed by foreign organizations/governments, or project offers significant unique health research opportunities to advance U.S. military medicine and benefit Service Members, Veterans, and their Families.

Section A: Senior/Key Personnel

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key personnel 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 Research & Related Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).

- **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.***

- **Level of Effort (Calendar, Academic, and Summer Months):** For each senior/key person, including unpaid personnel, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.

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

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the 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, other federally approved rate agreement, or other policy document).

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

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

Section B: Other Personnel

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

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

- **Level of Effort (Calendar, Academic, and Summer Months):** For each project role category, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.

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

- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the 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).

- **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 1 year and a per-unit acquisition cost that equals or exceeds the lessor of (a) $5,000 or (b) the awardee's or subawardees' capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

- Special test equipment to be fabricated for specific research purposes and its cost.

- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.

- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor/awardee 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:

- 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 justified with additional documentation and is subject to approval by the Contracting/Grants/Agreements Officer.

- 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 justified with additional documentation and is subject to approval by the Contracting/Grants/Agreements Officer.

- 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 2 days and including up to two overnight stays, at the Contracting Officer's Representative's/Grant 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, Maryland area but could occur elsewhere in the United States.

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

- **Materials and Supplies: "Materials and 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. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

    - If a computer/software purchase is requested, include the following in the budget justification:

        - Detailed explanation for why purchase of computer/software is required to complete the proposed research project

        - Statement verifying that the requested computer/software is not currently available for use by the PI

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

- **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.

- **Automated Data Processing (ADP)/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates. See the "Materials and Supplies" bullet above regarding the purchase of computers.

- **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 Research & Related Subaward Budget Attachment(s) Form.

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

All direct and indirect costs of any subaward must be included in the direct costs of the

primary award. No budget will be approved by the government exceeding the indirect rate exceeding the organization's negotiated rate.

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

- **Alterations and Renovations:** Alteration and renovation 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.***

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

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

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

Section H: Indirect Costs: The indirect costs category may include F&A costs, overhead, General and Administrative, 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.

For assistance agreements, in accordance with 2 CFR 200.414(f), any non-federal entity that does not have a current negotiated (including provisional) rate, may elect to charge a de minimis rate of 10% of modified total direct costs. Costs must be consistently charged as either indirect or direct costs but may not be double charged or inconsistently charged as both. If this methodology is chosen, it must be used consistently for all federal awards until such time as the non-federal entity chooses to negotiate for a rate.

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

Organizations can also visit the DHHS (https://www.hhs.gov/about/agencies/asa/psc/indirect-cost-negotiations/index.html), the Office of Naval Research (https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award), and the Defense Contract Audit Agency (https://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 or Research Other Transaction Agreement (OTA), either by the recipient/awardee or subrecipient/subawardee, is prohibited. For contracts, statutory limits for fees are specified in FAR 15.404-4.

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. 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 the Project/Performance Site Location(s) form. Each additional research site requesting funds will require a subaward budget.

7. Research & Related 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 Research & Related Subaward Budget Attachment(s) Form.

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

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

If collaborating with a DOD military facility, do not complete this form; complete the Suggested Intragovernmental/Intramural Budget (Section 8, below).

8. Suggested Intragovernmental/Intramural Budget

This section addresses requirements and procedures when a military facility will be a collaborator in performance of an extramural project.

Budget Form: Complete a separate "Suggested DOD Collaborating Military Facility Budget Format," for each military facility involved in the project, which is available for download on the eBRAP "Funding Opportunities and Forms" web page (https://eBRAP.org). Do not complete the grants.gov Research & Related 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. Extramural organizations may provide personnel to work at intramural DOD partnering organizations. The extramural personnel costs should not be included here but on the organization's Research & Related Budget Form (Sections A and B).

- **Travel:** Include costs to be incurred by DOD civilian and military personnel. However, **these costs cannot be reimbursed through the extramural award.** All approved travel costs of DOD military and civilian employees will be paid by the government through a direct fund transfer. 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 should not be included on the Suggested DOD Collaborating Military Facility Budget Format.

- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DOD-established reimbursement rates (e.g., IRB fees, IACUC fees), the military facility's Resource Manager/Comptroller/Task Area Manager or equivalent Business Official 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 Resource Management (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 of the form).

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 their 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 DOD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: If possible, the USAMRDC'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 awardee.

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRDC 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 include 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; and the Comptroller's (or equivalent) ability to accept and process award funds appropriately.

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

Technology Transfer: The Military Facility researcher(s) should also coordinate with their 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 awardee before work between the organizations 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.

B. Submission to Grants.gov

Grants.gov recommends submitting the application package ***at least 24-48 hours prior to the close date*** to provide time to correct any potential technical issues that may disrupt the application submission.

All proposals/applications must be received by the deadline indicated on the first page of the BAA (Section I, Overview of the Funding Opportunity). Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the proposal/application is successfully received by Grants.gov. The applicant AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the proposal/application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the proposal's/application's timely submission.

C. Applicant Verification of Grants.gov Submission in eBRAP

The full proposal/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 full proposal/application, PIs will receive an email notification of this status and will be able to view and modify proposal/application components in eBRAP. During the proposal/application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Research & Related Budget Form***, may be modified. See the BAA for specific full proposal/application submission and 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. ***The proposal/application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-proposal/ pre-application and proposal/application submission process.*** Inconsistencies may delay proposal/application processing and limit or negate the ability to view, modify, and verify the proposal/application in eBRAP.

After eBRAP has processed the full proposal/application and prior to the end of the proposal/ application verification period, select components of the full proposal/application package submitted to Grants.gov, ***with the exception of the Project Narrative and Research & Related Budget Form***, may be modified.

See the first page of the BAA for specific full proposal/application submission and proposal/ application verification deadlines.

Following retrieval and processing of the Grants.gov proposal/application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov proposal/application submission. eBRAP will validate retrieved files against the specific BAA requirements, and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the

applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA.

 ***eBRAP does not confirm the accuracy of the file content or the submission package.***

If either the Project Narrative or the Research & Related Budget fails eBRAP validation or if the Project Narrative or the Research & Related Budget need to be modified, an updated Grants.gov submission package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the proposal/application submission deadline. The full proposal/application submission deadline and the end of the proposal/application verification period in eBRAP are stated in the BAA.

D. Proposal/Application Tracking

After a Workspace package has been successfully submitted, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission. Participants can also find the Grants.gov Tracking Number on the Manage Workspace page, under the "Details" tab. The submission of a Workspace package can be tracked from Workspace or by visiting Grants.gov (https://www.grants.gov/web/grants/applicants/track-my-application.html) and entering the Tracking Number.

APPENDIX 1

REGULATORY REQUIREMENTS

A. Safety and Environmental Requirements

Based on recent changes to DOD compliance requirements (Department of the Army Pamphlet [DA PAM] 385-69, DA PAM 385-10, 32 CFR 651, September 6, 2012), provisions previously required for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, Biological Select Agents or Toxins, specific chemical agent(s), or pesticides outside of an established laboratory. The USAMRDC Office of Surety and Environment will identify any need for compliance review and documents must be submitted upon request.

Additional information is available at:
https://mrdc.health.mil/index.cfm/resources/researcher_resources/safety.

B. Research Protections Review Requirements

The USAMRDC Office of Human and Animal Research Oversight (OHARO) ensures that research conducted, contracted, sponsored, supported, or managed by the DOD and involving animals, human subjects, human data, human anatomical substances, and/or human cadavers is conducted in accordance with federal, DOD, Defense Health Agency, IACUC, USAMRDC, and international regulatory requirements. PIs and applicant organizations **may not commence performance** of research involving any of the above until regulatory documents are submitted **and** approved by the respective USAMRDC OHARO office(s) to ensure that DOD regulations are met. All expectations described below are consistent with DoD Instruction (DoDI) 3216.01, "Use of Animals in DoD Programs," and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research."

Organizational protocol approvals (e.g., IACUC or IRB approval) are not required at time of application submission unless otherwise noted in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding. Applicants are encouraged to review the "Guide for Funded Investigators" that is available on the eBRAP "Funding Opportunities and Forms" page, and the other referenced websites below for additional information about post-award processes and requirements.

Additional information is available on the OHARO page.

Animal Care and Use Review Office

All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC's OHARO ACURO, in addition to the local IACUC of record, prior to using DOD funds to start work with animals. This includes reviewing and approving amendments to ongoing projects that will use DOD funds. When requested, PIs must submit the

institutionally approved animal use protocol, documentation of IACUC approval of that protocol, and the completed ACURO Appendix. PIs should ***allow 2 to 3 months for the ACURO review and approval processes.***

Site Visits: The ACURO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to USAMRDC representatives as a part of their responsibility to protect animals in research. The ACURO cannot travel to any country that is designated as Level 4 (Do not Travel) or a foreign country of concern by the U.S. Department of State; ***therefore, they are unable to approve animal studies proposed in those areas.*** The ACURO will consult with USAMRDC Headquarters for any country that is designated as Level 3 (Reconsider Travel) by the Department of State or Department of Defense. The term "foreign country of concern" means the People's Republic of China, the Democratic People's Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the Department of State (42 USC § 19221(a)(1)). ***Due to these restrictions, applicant organizations should not propose to subaward, utilize contracting research organizations, or collaborate with investigators performing animal studies in any country that is designated as Level 4 (Do not Travel) or a foreign country of concern by the U.S. Department of State.*** Any application selected for award proposing animal studies in a restricted country will be required to modify their request during award negotiations. If an applicant is unable to modify the subaward, contracting research organization or collaborator within the original budget amount requested, their selection for funding will be ***forfeit***.

For current information about ACURO policies, detailed guidance, and the ACURO Appendix, visit the ACURO page.

Send questions via email to the ACURO (usarmy.detrick.medcom-usamrdc.other.acuro@health.mil).

Office of Human Research Oversight (OHRO)

All DOD-funded research involving new and ongoing research with human subjects, data, specimens, and/or cadavers must be reviewed and approved by the USAMRDC OHARO, OHRO, prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee review. PIs should ***allow up to 3 months to complete the OHRO regulatory review and approval process following submission of all required and complete documents to the OHRO.*** Studies taking place in international settings may require additional time for completion of OHRO reviews.

For current information about OHRO policies, detailed guidance, and submission forms, visit the OHRO page.

Questions regarding applicable research protection regulations, policies, and guidance should be directed to the reviewing IRB or the OHRO (usarmy.detrick.medcom-usamrmc.other.hrpo@health.mil).

C. Human Subjects Research

Applicants should keep in mind the following key requirements as they plan any DOD-funded human subjects research. Additional information is provided in the "Information for Investigators – Human Subjects Research" guidance document on the OHRO website.

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance (FWA) or DOD Assurance (Intramural DOD institutions only).

- **Informed Consent Language:** 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 Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom protected health information may be disclosed.

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

  Individuals not legally competent to provide their own informed consent in advance (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled in research studies where there is an intervention or interaction with the subjects for the primary purpose of obtaining data regarding the effect of the intervention or interaction, unless participation in the research includes an intent to benefit each subject enrolled in the study, to include subjects enrolled in study placebo or usual care arms. Studies designed in a manner that permits all subjects to potentially benefit directly from study treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements.

- **10 USC 980 Waiver:** If the applicant proposes to conduct a clinical trial engaging trauma patients or other planned emergency research under the 21 CFR 50.24 provisions for exception from informed consent, the applicant should plan for 3-6 months of additional time for the OHARO OHRO to review the submission and request Army Surgeon General or DOD approval of a waiver of the requirements of 10 USC 980.

D. Research Involving the Secondary Use of Human Data and/or Human Anatomical Substances

All USAMRDC-supported research involving the secondary use of human data and/or human anatomical substances (i.e., specimens) must be reviewed for compliance with federal and DOD human subjects protection requirements and approved by the OHRO prior to using DOD funds for any such research. ***Research involving the use of human data and/or human anatomical substances not otherwise subject to IRB review (e.g., "exempt" research) still requires PIs to submit the DOD-funded human data/specimens research to the IRB to obtain a determination letter (e.g., stating that the project does not constitute "human subjects research" or can be considered "exempt human subjects research") from the IRB confirming this status.***

Detailed guidance and instructions on OHRO review of DOD-funded research activities involving access, use, and analysis of human data and/or human anatomical substances is provided in the "Information for Investigators – Research with Data/Specimens" guidance document on the OHRO website. This guidance document also includes a detailed discussion on the types of human data, cell lines, specimens, etc., that do not require OHRO review and approval.

E. Use of Unique or Regulated Sample Types

Fetal Tissue: OHRO submission and review is required for research using fetal tissue and cell lines derived from fetal tissue. Note that use of cord blood or materials derived from placenta are not considered fetal tissue. Due to state and federal laws that govern research use of fetal tissue, the OHRO will confirm that the institutional review determined:

- the written consent of the mother was obtained;
- the fetus can be used for research;
- the use of fetal material is required for the research and other materials cannot be substituted;
- and the source of the materials is documented (institution, clinical providers, nonprofit repositories, etc.)

Additional approvals are required for research with fetal tissues in accordance with DoDI 3216.02. Investigators should allow for additional time to receive OHRO and higher-level approval.

Human Embryonic Stem Cell Lines: The OHRO adheres to the NIH policy requirements and requires submission and review of research on existing human embryonic stem cell lines and derivation of new human embryonic stem cell lines. Due to the ethical issues related to research use of embryonic stem cells, OHRO recommends investigators who plan to conduct research with embryonic stem cells consult the OHRO for input during the proposal process.

Research Involving Use of Human Embryos: Per DoDI 3216.02, DOD funds cannot be used to support or be used for the creation of a human embryo or embryos for research purposes (to include gene editing research) or for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than

that allowed for research on fetuses in utero in accordance with 45 CFR 46.204(b) and 42 USC 289g(b)

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

Research, Development, Test and Evaluation (RDT&E), education, or training activities involving human cadavers or human anatomical substances obtained from cadavers (postmortem samples) shall not begin until the USAMRDC OHARO grants approval in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training. The USAMRDC OHARO is the Action Office for this Army policy. **Additional requirements apply to use of cadaveric specimens obtained from outside the U.S. and activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.**

G. Large-Scale Genomic Data (LSGD) Collected from DOD-Affiliated Personnel

Disclosure of DOD-affiliated personnel's LSGD may pose a national security risk; accordingly, such research (including the secondary use or sharing of identified or de-identified data or specimens) requires inclusion of administrative, technical, and physical safeguards commensurate with risk. LSGD efforts must undergo security review and additional approvals by the USAMRDC OHARO, USAMRDC Headquarters, and DOD Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical, and physical safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors. DOD-funded research involving LSGD collected from DOD-affiliated personnel may require that the performer obtain a NIH Certificate of Confidentiality. If selected for funding, performers must take these additional requirements into consideration when developing timelines and milestones.

H. Additional Information/Requirements

OHRO Submission: Any protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the approved SOW. If the DOD-funded activities have been added to an ongoing/existing protocol that is not DOD-funded, OHRO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DOD award.

Any protocol submitted for OHRO review must include only those activities funded by the DOD, as referenced in the approved SOW.

Single IRB Requirement: As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research must rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with 45 CFR 46.114(b). ***This includes certain types of work with human data and/or human specimens if that work has not been/will not be deemed exempt.*** If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of application

submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single POC for regulatory submissions and requirements.

Research Involving International Performance Sites: In addition to host nation and local requirements, U.S. research regulatory requirements apply when DOD-funded research is conducted outside the U.S.

Site Visits: The OHRO 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 USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner to protect the confidentiality of subject information.

Research Involving FDA-Regulated Products: Research evaluating the safety or effectiveness of drugs, devices, or in vitro diagnostics requires IRB review in accordance with 21 CFR 50 and 21 CFR 56 and 21 CFR 312 and/or 21 CFR 812, as applicable.

Clinical Trial Registry and Data Upload: The USAMRDC requires all funded Applicable Clinical Trials to register on ClinicalTrials.gov. When entering study identification information, include the eBRAP log number as a Secondary ID for the study with the following designation: "-eBRAP Log Number" (e.g., -DM25####). Ensure that "Defense Health Agency – Science and Technology Portfolio Management Branch (DHA-STPMB)" is entered as a collaborator for the study due to their role as a funding source. Additional instructions for registering a clinical trial and using clincaltrials.gov can be found here. As described in Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11), studies that meet the definition of an Applicable Clinical Trial are required to submit study result information to clinicaltrials.gov.

Performers conducting phase 3 clinical trials must submit results of analyses of group differences on the basis of sex, race, and/or ethnicity to ClinicalTrials.gov at the time of final report submission. If final analyses of sex and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

Posting of Informed Consent Forms: Studies that meet the definition of a **clinical trial** must post an IRB-approved informed consent form used to enroll subjects on a publicly available Federal Web site (e.g., ClinicalTrials.gov, Regulations.gov). The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subjects.

I. DoD Instruction Use of DOD or Department of Veterans Affairs (VA) Resources

If the proposed research involves access to active-duty military patient populations and/or DOD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to the target active-duty military patient population(s) and/or DOD resource(s) or database(s) should be

confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs/Co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DOD or VA patient populations, resources, or databases may only be obtained by collaboration with a DOD or VA investigator who has a substantial role in the research and may not be available to a non-DOD or non-VA investigator if the resource is restricted to DOD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA. If access cannot be confirmed at the time of proposal/application submission, the government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

APPENDIX 2

REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION

A. 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:

- Service Contract Reporting (SCR):
    - SCR is now a requirement of all DOD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal/application 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. SCR costs/price will not be evaluated as part of the total evaluated proposal/application 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 report the information outlined in DFARS 252.204-7023 for services performed during the preceding government fiscal year under the contract or order that exceed the thresholds established at DFARS 204.1703 and DFARS PGI 204.1703, using the following web address: https://www.sam.gov/SAM.
    - 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.
- Technical/Scientific:
    - In addition to annual progress reports, the Terms and Conditions of the award will indicate any additional reporting required.
    - Final Technical Report/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://ebrap.org/eBRAP/public/Program.htm and as an attachment to a standard post-award progress report under Special Reporting Requirements if required by the terms and conditions of the award.

- The USAMRDC research progress reporting requirements and instructions can be found at https://mrdc.health.mil/index.cfm/resources/researcher_resources/reporting/technical.

- Fiscal (SF 425 "Federal Financial Report") (assistance agreements only):
  - Quarterly and/or annual reports
  - Final report

- Regulatory:
  - Research Involving Human Subjects: For DOD awards that include funding to support research with human subjects, the USAMRDC's OHRO requires submission of institutional continuing review reports and study event and modification reports. Instructions are found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.
  - The USAMRDC's OHRO does not require submission of local IRB annual continuing review materials for studies that no longer require continuing review under the 2018 Revised Common Rule (49 CFR Part 11).
  - Research Involving Animals: For DOD awards that include funding to support animal studies, staff from the USAMRDC's ACURO will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@health.mil.
  - Public Health Service (PHS) Inclusion Enrollment Report: This is used to report the sex, race, and ethnicity of study participants that will be enrolled in the clinical research (both planned and actual). The PHS Inclusion Enrollment Report is a three-page fillable PDF form that may be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm and completed for submission with the application. The directive outlining the references for this requirement is found at https://cdmrp.health.mil/pubs/pdf/CDMRP%20IWAM%20Directive_Revised_MAR2025_signed.pdf.

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

B. Post-Award Organization and Principal Investigator Changes

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

Transfer of Assistance Agreement: Unless restricted by the BAA, a change in organizational affiliation will be considered on a case-by-case basis by the USAMRAA Grants Officer. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire proposal/application on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at

risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Transfer of OTA: Transfer of an OTA award to a new organization is not permitted.

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

C. Disclosure of Proprietary or Confidential Information

Do not include proprietary or confidential information in a pre-application/pre-proposal or abstract. Proprietary information should only be included in a full proposal/application if necessary for 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 proposal/applications may be subject to public release under FOIA.

Proposals/applications for funded projects will be subject to public release under the 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.

D. Marking of Proprietary or Confidential Information

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

E. Award Notices

Awards are made to organizations, not to individual PIs. The USAMRDC 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 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 U.S. government (31 USC 6303). The award type, along with the start date, will be determined during the negotiation process.

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 United States, instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

3. **An OTA** is appropriate to carry out certain prototypes, research, and production projects. Other Transaction authorities were created to provide the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments.

4. After email notification that proposal/application review results can be found on 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, Agreements, 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 USAMRAA Contracting, Agreements, or Grants Officer is the official authorizing document.

F. Inquiry Review Process (IRP)

Although not required by law or acquisition regulation, the USAMRDC offers a courtesy to all applicants in an effort to maintain high integrity in its review processes. If a proposal/application is not recommended for funding and a factual or procedural error is believed to have occurred during the review of the proposal/application, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the proposal/application, as defined below:

- **Factual error:** An error in the review (peer or programmatic) that is restricted to, or based on, fact. Differences of opinion between reviewers or between reviewer(s) and an applicant are not factual errors.

- **Procedural error:** An error in the review (peer or programmatic) that is restricted to review process adherence. Review process did not follow the procedures as outlined in the BAA describing peer and programmatic review (e.g., documents requested in the BAA and submitted with the original proposal/application were left out of the peer or programmatic review package).

Inquiries should be submitted through the eBRAP Help Desk at help@eBRAP.org. An inquiry review panel consisting of USAMRDC staff will determine whether an error occurred in either peer or programmatic review. An application re-review (peer or programmatic) may be recommended as corrective action in the case of an error determination, per the following guidelines. These guidelines may not cover all possible scenarios in which the peer review score and/or any described "weaknesses" had no bearing on the "not fund" recommendation. The guidelines are:

1. If the perceived factual error pertains to an application that received an outstanding (1.0-1.5) or excellent (1.6-2.0) overall peer review score and was not recommended for funding strictly for programmatic reasons (e.g., "limited impact relative to other submissions" or "portfolio composition"), a re-review is not required.

2. If the IRP panel can clearly determine that the perceived factual error had insignificant or no impact on peer review scores (e.g., perceived error was noted as a strength in the peer review summary statement) and had no bearing on the second-tier programmatic decision to not fund an application, a re-review is not required.

3. If the conditions in guidelines 1 and 2 are not met, and the IRP panel determines that there is indeed a factual or procedural error with a potential impact on the funding recommendation, a re-review is required.

A recommendation for application re-review is not a guarantee of funding.

The final determination of the IRP and the funding decision are not subject to appeal. Questions related to the IRP prior to or after submitting an inquiry should be directed to the eBRAP Help Desk at help@eBRAP.org.

G. Information Service

Applicants may use the technical reference facilities of the U.S. Department of Commerce National Technical Information Service (https://www.ntis.gov) and/or the Defense Technical Information Center (DTIC) to obtain information about existing research to avoid duplication of scientific and engineering effort.

H. Freedom of Information Act Requests

The FOIA (5 USC 552) provides a statutory basis for public access to official government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (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 submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRDC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of

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

I. Information Release

An awardee 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. Certain research topics may require prior approval by the contracting officer prior to publishing, reference DFARS 252.204-7000.

The following statements must be included in all information releases:

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

"This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of (*insert total costs*), through the (*insert program name*) under Award No. (HT9425231XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."

(2) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents, and information specified on the ACURO website. (https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro)

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

(4) "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the Centers for Disease Control and Prevention-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (https://www.cdc.gov/safelabs/resources-tools/biosafety-resources-and-tools.html)

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

J. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DOD definition of "Contracted Fundamental Research." The results of this research are to be

unrestricted to the maximum extent possible. It is at U.S. government discretion to fund research with Budget Activity 3 (6.3) without placing restrictions on publication or personnel. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

K. Sharing of Proposal/Application Information

The USAMRDC may share proposal/application information with other federal funding agencies (e.g., NIH, NSF, VA) to inform funding priorities and decisions, and to increase transparency. By sharing and leveraging this information, duplication of effort can be avoided, allowing for the support of more investigators with federal funds. The USAMRDC believes that such sharing may allow for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on USAMRDC-funded awards including awardee information and published results are shared on DTIC.

L. Sharing of Data and Research Resources

The USAMRDC intends that information, data, and research resources generated under awards funded by the BAA be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

Data and research resources generated by funded research should be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public. The expectations for sharing of data and research resources apply to all research funded by the BAA. This includes all data and research resources generated during the project's period of performance as annotated in the assistance agreement or contract:

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large research data collections 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 https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/data-management-and-sharing-policy-overview)

- 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 https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policy/data-management-and-sharing-policy-overview)

- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://sharing.nih.gov/other-sharing-policies/research-tools-policy)

Data and research resources generated from USAMRDC-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 efforts can be avoided, allowing for the support of more investigators with federal funds. The USAMRDC 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): If the project includes TBI research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (https://fitbir.nih.gov).

- Clinical Trials: If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (https://www.clinicaltrials.gov/).

For unique data-sharing guidelines and requirements, refer to the instructions in the BAA.

M. Property/Equipment

Contracts: Reference FAR Part 45 and DFARS Part 245. Contractors are ordinarily required to furnish all property necessary to perform Government contracts.

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

N. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (35 USC, 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 DFARS 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: DoDGARs 34.25 and 2 CFR 200.315-316

APPENDIX 3

QUALIFICATION AND RESTRICTIONS INFORMATION

A. Contractor/Recipient Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. According to the standards of DoDGARs 22.415, a potential qualified recipient must (1) have the management capability and adequate financial and technical resources, given those that would be made available through the grant or cooperative agreement, to execute the program of activities envisioned under the grant or cooperative agreement; (2) have a satisfactory record of executing such programs or activities if it is a prior recipient of an award; (3) have a satisfactory record of integrity and business ethics; and (4) be otherwise qualified and eligible to receive a grant or cooperative agreement under applicable laws and regulations (see DoDGARs 22.420(c)). For contracts, please refer to FAR 9.104-1 and DFARS 209.104-1.

The USAMRDC utilizes the Exclusions within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at https://www.sam.gov/SAM/. The USAMRDC also reviews and considers information about the applicant in the Office of Management and Budget (OMB)-designated integrity and performance system, currently the Federal Awardee Performance and Integrity Information System (FAPIIS), prior to making an award, as described in the BAA, Section II.E.3.

B. Eligibility Information

Effective January 1, 2016, prior to making an award where the federal share is expected to exceed the simplified acquisition threshold (currently $250,000) over the period of performance, the federal awarding agency is required to review information regarding the recipient that is available through 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 5-year period and that were connected with performance of a federal award. Recipients are required to disclose semiannually the information about the criminal, civil, and administrative proceedings that Section 872(c) describes. Reference Federal Register Notice, Vol. 80, No. 140, Wednesday, July 22, 2015.

General eligibility for investigators, organizations, and agencies:

- Eligible Investigators: Includes all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization. ***Note: Awards are made to organizations only, not 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 United States: Local, state, and federal government agencies are eligible to the extent that proposals/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. J-1 Visa Waiver

Each organization, including organizations located outside of the United States, are responsible for ensuring that the personnel associated with any proposal/application recommended for funding are able to complete the work without intercession by the Department of Defense for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

Note: The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (https://www.state.gov/state-sponsors-of-terrorism/). Additional information on J-1 Visa Waivers can be located at the following Department of State website: https://travel.state.gov/content/travel/en/us-visas.html.

D. Conflict of Interest

1. Contract Awards

Organizational and Consultant COIs: Contracts must comply with the requirements found in FAR Subpart 9.5, Organizational and Consultant Conflicts of Interest. An organizational 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 Subpart 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/application, 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 COI 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 Restrictions

There are certain post-employment restrictions on former federal officers and employees as defined in 18 USC 207. Post-employment restrictions may exist if a former federal officer or employee participates in the proposed project; the situation should be addressed with the USAMRDC Office of the Staff Judge Advocate at Fort Detrick, Maryland, (https://installations.militaryonesource.mil/military-installation/fort-detrick/legal/legal-assistance) prior to expending time and effort in preparation of a proposal/application.

APPENDIX 4

FORMATTING GUIDELINES

All pre-proposal/pre-application and 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 among the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** Each attachment to the full proposal/application forms must be uploaded as an individual file in the format specified in the BAA. All contributors to the proposal/application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing proposal/application components. The use of different software versions will result in corruption of the submitted file.

- **Font Size:** 12 point, not condensed.

- **Font Type:** Times New Roman.

- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).

- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).

- **Margins:** At least 0.5 inch (1.27 cm) in all directions.

- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).

- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-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; bitmap and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.

- **Scanning Resolution:** 100 to 150 dots per inch.

- **Internet URLs:** URLs, or web addresses, 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:** Individual attachments should be no larger than 20 MB. ***If the file size for the entire Grants.gov submission 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 5

NATIONAL POLICY REQUIREMENTS

The National Policy Requirements are available in full text at https://www.onr.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. For additional regulatory requirements regarding safety, surety, and environmental requirements, and for use of animal and human subjects in research, refer to Appendix 1 of this General Submission Instructions.

A. Certification

Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over $100,000. Submission of this certification is required by 31 USC 1352 and is a prerequisite for making or entering into an award over $100,000.

Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (Research & Related) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

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

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

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including 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 31 USC 1352. Any person who fails to file

the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

B. Representations

1. Representations for Application Submission

Extramural applicants are required to complete the representations below and submit with each proposal/application only if the organization is a Corporation and the response to item (2) or (3) is in the affirmative. The form for completion and submission is posted in eBRAP (https://ebrap.org/eBRAP/public/Program.htm). Upload the form into Grants.gov under Attachments.

Representations Regarding Unpaid Federal Tax Liabilities and Conviction of Felony Criminal Violations Under Any Federal Law

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

(1) Is ___ Is not ___ a Corporation ("Corporation" means any entity, including any institution of higher education, other non-profit organization, or for-profit entity that has filed articles of incorporation). If the organization is a corporation, complete (2) and (3) below.

(2) Is ___ Is not ___ a Corporation 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.

(3) 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 (2) or (3) of the above representations, the applicant is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the government's interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

In accordance with DOD appropriations, the following representation is required. The applicant, by its signature on the SF424 Research & Related Form, represents:

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

By submission of its proposal/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, Public Law 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 SF 312, Form 4414, or any other form issued by a federal department or agency governing the nondisclosure of classified information.

National Policy Requirements

The recipient must comply with the following requirements, as applicable. The full text of National Policy Requirements is available at https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements
- FY21 National Defense Authorization Act Section 223(a), (a1) 18 USC 1001

2. Representations and Certifications for Contracts

In accordance with FAR 4.1102 and 4.1201, proposers anticipating a procurement contract must complete electronic annual representations and certifications at https://www.sam.gov/. The annual representation and certifications must include both FAR and DFARS provisions. Complete the following representation and submit with each proposal/application as required for contracts.

APPENDIX 6

ACRONYM LIST

ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
BAA	Broad Agency Announcement
CAGE	Commercial and Government Entity
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
COR	Contracting Officer's Representative
CRADA	Cooperative Research and Development Agreement
DA PAM	Department of the Army Pamphlet
DFARS	Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic Acid
DOD	U.S. Department of Defense
DoDI	Department of Defense Instruction
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
eBRAP	Electronic Biomedical Research Application Portal
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FITBIR	Federal Interagency Traumatic Brain Injury Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
FY	Fiscal Year
GOR	Grant Officer's Representative
GSA	General Services Administration
HIPAA	Health Information Portability and Accountability Act
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
IRP	Inquiry Review Process
JPEG	Joint Photographic Experts Group

LSGD	Large-Scale Genomic Data
MB	Megabyte
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
NSPM-33	National Security Presidential Memo – 33
OEM	Original Equipment Manufacturer
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
OMB	Office of Management and Budget
ORCID	Open Researcher and Contributor Identification
OTA	Other Transaction Agreement
PD	Project Director
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
POC	Point of Contact
PSC	Product Service Code
R&R	Research and Related
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SCO	Senior Contracting Official
SCR	Service Contract Reporting
SF	Standard Form
SFLLL	Standard Form LLL (Disclosure of Lobbying Activities)
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs
WAV	Waveform Audio