General Submission Instructions for Funding Opportunity Number: HT9425-23-S-SOC1

Broad Agency Announcement
for Extramural Biomedical and Human Performance Research and Development
Fiscal Year 2023 – Fiscal Year 2028

Department of Defense

United States Special Operations 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 Broad Agency Announcement for specific instructions.

B. Current Funding Opportunity Announcement

The Fiscal Year 2023 – Fiscal Year 2028 (FY23-FY28) U.S. Special Operations Command (USSOCOM) Broad Agency Announcement (BAA) can be found by searching Grants.gov

(http://www.grants.gov/) using the Funding Opportunity Number **HT9425-23-S-SOC1** or the Catalog of Federal Domestic Assistance (CFDA) number **12.420 Military Medical Research and Development.**

USSOCOM utilizes the tools and processes provided by 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 Officials 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 by email programs, keep your email address up to date in eBRAP and Grants.gov and place the following domains into your safe list: army.mil, us.army.mil, *.mail.mil, health.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 to Grants.gov.

On occasion, the Grants.gov proposal package may be updated or changed. The applicant must use the latest version of the Grants.gov submission package; proposals submitted with a different version of the Grants.gov submission package will be rejected by Grants.gov. **Sign up in Grants.gov (http://www.grants.gov/) for "Send me change notification emails" by following the link on the Synopsis page for the BAA or by responding to the prompt *provided by Grants.gov when first downloading the Grants.gov 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 through eBRAP, should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time. Response times may vary depending upon the volume of inquiries. Be advised that the eBRAP Help Desk is unable to provide technical assistance with Grants.gov submission.

   Phone: 301-682-5507

   Email: **HELP@EBRAP.ORG**

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

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

   Email: **SUPPORT@GRANTS.GOV**

II. REGISTRATION AND SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) Pre-proposal submission through eBRAP (https://eBRAP.org/) and (2) full proposal submission through a Grants.gov Workspace or eBRAP, depending on the type of application being submitted. General registration information is provided below. For detailed instructions, refer to the eBRAP User Guide (https://ebrap.org/eBRAP/public/UserGuide.pdf) for eBRAP registration, and www.grants.gov for Grants.gov registration.

Submission of Proposals 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.

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

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

A. eBRAP Registration

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

eBRAP does not confirm the accuracy of file content!

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

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

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

PI's name and email address in the eBRAP pre-proposal/pre-application submission must match the information provided in Standard Form 424 (SF424) of the Grants.gov submission package. For the Business Official to view/modify files, the Business Official's name and email address in the eBRAP pre-proposal submission must match the information provided in the SF424 of the Grants.gov submission package.

During pre-proposal 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. The Business Official's registration must be completed prior to the full proposal deadline to allow the Business Official to view/modify the full proposal files in eBRAP after submission.

During pre-proposal 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.

B. Submission Dates and Times

This BAA is continuously open for a 5 year period, from 1 August, 2023 through 31 July, 2028, 11:59 p.m. Eastern Time. **Pre-proposals are required** and may be submitted at any time throughout the 5-year period.

C. Content and Form of pre-application Submission

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

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

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

Tab 2 – Application Contacts: Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of 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 organization. Click on "Add Organizations to this pre-application." The Business Official must be either selected from the eBRAP list or invited in order for the pre-proposal to be submitted.

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

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

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

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

Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in any pre-proposal and full proposal, including, but not limited to, concept design, proposal 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 in performance of the research), this prohibition is not applicable; however, those Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

To preserve the integrity of its peer and programmatic review processes, the USSOCOM discourages employees or contracted personnel performing proposal review functions from participating or submitting proposals. For FY23-FY28, the peer review contractor is General Dynamics Information Technology (GDIT). The programmatic review contractor may vary. Proposals that include names of personnel from a review contractor may be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Questions related to this topic should be directed to the eBRAP Help Desk at help@eBRAP.org or 301-682-5507. Refer to Appendix 3 for additional information.

Tab 4 – Conflicts of Interest (COI's): 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 (including those with whom the PI has a personal or professional relationship). Click on "Save."

Tab 5 – Required Files: Upload all documents as PDF as specified in the BAA. Documents should conform to the formatting guidelines outlined in Appendix 4. Click on "Upload."

- eBRAP will truncate characters exceeding the limit specified for each data field as specified in the BAA.

- eBRAP will not allow a document to be uploaded in the Required Files tab if the number of pages exceeds the limits specified in the BAA.

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

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

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

III. CONTENT AND FORM OF APPLICATION SUBMISSION FOR RESEARCH PROPOSALS

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

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

USSOCOM 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. The Project Narrative and Budget Form cannot be modified during the proposal verification period.

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

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, e.g., obtaining a Unique Entity Identifier (UEI) number via registration as an Entity in the System for Award Management (SAM).

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

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

1. UEI and SAM

As of April 4, 2022, all organizations applying online through Grants.gov must register with the SAM and will receive a(UEI number. Failure to register with SAM will prevent your organization from applying through Grants.gov. Applicant organizations and all subrecipient organizations must have an active registration in the (SAM) number to submit proposals to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit proposals through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the proposal submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at 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 as a basis for making a Federal award to another applicant.

2. SAM Registry

The applicant organization must be registered as an entity for **all awards** in SAM (https://www.sam.gov) and receive confirmation of an "Active" status before submitting a proposal through Grants.gov. The SAM validates organization information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an Electronic Business (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 submission deadline.*** An organization can register in SAM online at https://www.sam.gov/. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. Allow 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 as a basis for making a Federal award to another applicant. ***Additional information and step-by-step registration directions are detailed in the SAM User Guide and***

other General Services Administration (GSA) training materials in the Help area at https://www.sam.gov/.

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

3. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE Code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration advances through the validation process. Foreign registrants in SAM must be assigned a 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/Request. On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

4. 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 application package. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before proposal submission, the AOR must be registered to submit on behalf of the organization at Grants.gov (https://www.grants.gov/web/grants/applicants/registration.html).

An AOR must first register with the Grants.gov credential provider at https://www.grants.gov/web/grants/applicants/registration.html 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 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 submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the proposal is current, accurate, and complete.

When applications are submitted through Grants.gov, the name of the organization's AOR that submitted the application is inserted into the signature line of the application, serving as the electronic signature. The E-Biz POC **must** authorize individuals who are able to make legally binding commitments on behalf of the organization as an AOR; **this step is often missed and it is crucial for valid and timely submissions**.

5. Grants.gov Workspace

Applicants must create a Workspace, which allows the 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 submission must include the completed Grants.gov submission package of forms associated with the BAA in Grants.gov (http://www.grants.gov/).

If the applicant decides not to apply by filling out webforms within the Workspace, individual PDF forms can be downloaded, saved, and uploaded to the Workspace. A compatible version of Adobe Reader must be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the same version of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. 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 must be resubmitted using a new Grants.gov submission package and a supported version of Adobe Reader prior to the proposal submission deadline. It is the applicant's responsibility to verify his/her Adobe Reader's compatibility with Grants.gov: https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html. A no-cost compatible version of Adobe Reader can be downloaded at http://get.adobe.com/reader/otherversions/. All contributors to the proposal must use matching compatible versions of Adobe software when editing and preparing proposal components outside the Workspace. The use of different software versions will result in corruption of the submitted file.

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 submission deadline.

A. Grants.gov Submission Package Components for Research Proposals

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

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

Block 1 – Type of Submission. For original submissions, select the "Application" box. For changes that must be made after the original submission, the complete Grants.gov submission package must be resubmitted with the "Changed/Corrected Application" box selected.

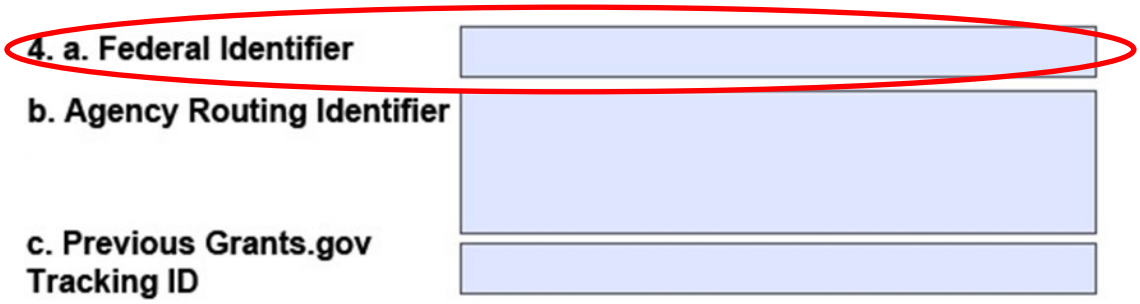
Block 2 – Date Submitted. Enter the date the proposal is submitted.

Applicant Identifier. Enter the submitting organization's Control Number, if applicable. If there is no Organization Control Number, leave this field blank.

Block 3 – Date Received by State and State Application Identifier. Not applicable.

Block 4a – Federal Identifier Box. Enter in your eBRAP log number assigned during pre-proposal 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/correct proposal, enter the Grants.gov Tracking Number for the original proposal.
- **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.
- **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 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. If outside the United States, select the appropriate country from the drop-down menu.

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

If a revised Project Narrative or 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 (R&R) Form prior to the full proposal submission deadline.

2. Attachments Form

Grants.gov does not validate for the presence of attachments on this Attachments Form. Following retrieval and processing of the Grants.gov proposal, eBRAP will notify the organizational representatives and PI by email to log into the eBRAP to view, modify, and verify the Grants.gov proposal submission. eBRAP will validate retrieved files against the BAA guidelines. Discrepancies will be noted in both the email and in the Full Application tab. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all proposal components and ensure proper ordering as specified in the BAA. See 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. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire 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 or for other guidance.

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

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

The following must be included as attachments to this form:

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

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

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 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.***

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

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

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.

Attachment 4: Lay Abstract: Attach as a PDF file named "LayAbs.pdf." Do ***not*** include proprietary or confidential information. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

Attachment 5: Statement of Work (SOW): Attach as a PDF file named "SOW.pdf." The SOW outlines and establishes the performance expectations and milestones for which USSOCOM 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: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. ***The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The SOW must be in PDF format prior to attaching. The Government reserves the right to request a revised SOW format and/or additional information.***

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

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); description of research with animals, human anatomical substances, and/or human subjects or cadavers to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. As applicable, estimated times to complete each task should include time for local USSOCOM and the U.S. Army Medical Research and Development Command (USAMRDC) regulatory review and approval, as shown below. Refer to Appendix 6 for additional information regarding regulatory review.
    - For studies involving human subjects, include a subtask that allows at least 2 to 3 months for regulatory review and approval by the 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 1 to 2 months for regulatory review and approval by the USSOCOM Veterinarian Review Office (VRO) and international regulatory requirements. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The VRO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol.

Questions concerning animal use and review should be directed to the USSOCOM VRO:
Phone: 813-826-6548; Email: socom_vet@socom.mil

- **Attachments 6-12: Additional Documents (as applicable):** Attach each as a separate PDF file, named as indicated in the BAA (e.g., "Impact.pdf," "Transition.pdf," etc.).

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

3. Research & Related (R&R) Personal Data

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

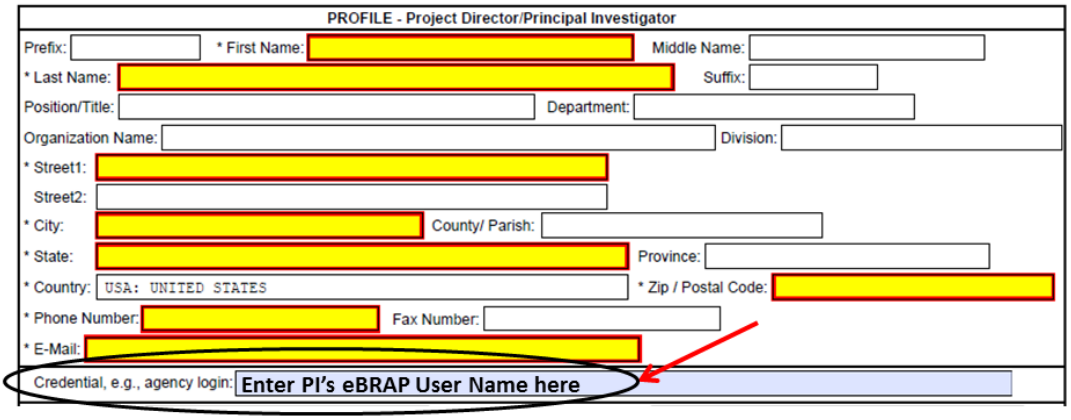
Each application must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the "Next Person" button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to merit 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)

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

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

Figure 2. PI's eBRAP User Name



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

- **PI Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the PI.
- **PI Previous/Current/Pending Support:** This file must be titled "Support_LastName.pdf," where "LastName" is the last name of the PI.
    - For all previous (award period of performance ending within the past 5 years), current, and pending (includes period of time awaiting funding status and/or period of time awaiting start date) research support, include the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting Officer, performance period, level of funding, brief description of the project's goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.
    - List all positions and scientific appointments, both domestic and foreign, held by senior/key personnel that are relevant to an application, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
    - Report all resources and other support for all individuals designated in an application as senior/key personnel – including for the PI and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, whether such support is provided through the applicant

organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel's research efforts.

- Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.
- Consistent with National Security Presidential Memoranda-33, individuals are required to disclose grants and 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 activity. Foreign government-sponsored talent recruitment program" is defined as an effort organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position).
- Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person- months) per year to be devoted to the project by the senior/key personnel involved.
- If there is no previous, current, or pending support, enter "None." An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Key Personnel Biographical Sketches:** Each file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the respective individual.
- **Key Personnel Previous/Current/Pending Support:** Each file must be titled "Support_LastName.pdf," where "LastName" is the last name of the respective individual. Refer to content requirements under "PI Previous/Current/Pending Support" listed above.
  - Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, laboratory space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.

5. Research & Related Budget

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

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

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 FAR Supplement Part 231
    - 2 CFR Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," implemented by Chapter XI of Title 2, CFR.
- **Award Funding/Maximum Obligation:**
    - **Contract Awards:** Reference contract funding regulations in FAR 32.7 and Defense Federal Acquisition Regulation Supplement (DFARS) 232.7.
- **Pre-Award Costs:** Pre-award costs may be allowable as follows:
    - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. An advanced agreement must be executed by the Contracting Officer prior to incurring any cost. Advanced Agreement Costs (Pre-Contract Costs) are referenced in FAR 31.205-32 and Advanced Agreements in 31.109.
- **Cost of Preparing Proposals:** The cost of preparing proposals in response to the BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals may be an allowable expense included in the indirect/facilities and administrative cost as specified in the organizations 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 based on the official rate in effect at the time of submission.

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

Budget Instructions: Complete the Research & Related Budget following the instructions below. Begin by entering the organizational 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. 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 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 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 Collaborating DoD Military Facility Budget Form(s). Include any Military Facility's direct and indirect costs on this form. Also, include the Military Facility's total costs (direct and indirect) on the Subaward/Consortium/Contractual Costs line of the Research & Related Budget Form (Section F.5.). See Section III.A.8, Collaborating with DoD Military Facilities, for additional information.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3.
- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
- **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.***

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

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
- **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most Federal agencies, funding cannot be applied toward Federal salaries; 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 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 of (a) $5,000 or more per unit, 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 well justified and is subject to approval.
- Costs for travel required for the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be well justified and is subject to approval.
- 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 (COR) request. The invitation and format for the IPR will be provided by the COR at least 90 days prior to the meeting. The meetings will generally be held in the MacDill Airforce Base, Florida 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:** Supplies means all tangible personal property, including a computing device, acquired under an award that does not meet the definition of equipment. The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing $5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.

  Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project.

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

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

  If 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) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. See Section III.A.8., Collaborating with DoD Military Facilities below, for more information.

  Subcontracts shall be submitted in accordance with FAR 19.704 as necessary.
- **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 (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and **are a minor portion of the overall budget**. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. **Costs for the construction of facilities are not allowable.**

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

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

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

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

In accordance with 2 CFR 200.414, a non-Federal entity that has never received a negotiated indirect cost rate, may elect to charge a de minimis rate of 10% of modified total direct costs. 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. Costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both.

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

Provide documentation to support the indirect cost rate (e.g., the current DHHS, Defense Contract Audit Agency [DCAA], Office of Naval Research [ONR] Rate Agreement, other Federally approved rate agreement, or other policy document) via eBRAP (https://eBRAP.org).

Organizations can also visit the DHHS (https://www.hhs.gov/about/agencies/asa/psc/indirect-cost-negotiations/index.html), the ONR (https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award), and the DCAA (http://www.dcaa.mil/) for additional information on indirect rates.

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

Section J: Fee: Statutory limits for fees are specified in FAR 15.404-4(c)(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 from **Federal agencies** must include in their budget justifications a **Federal Financial Plan.** The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

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

6. Project/Performance Site Location(s) Form

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

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

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

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

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

8. Collaborating with DoD Military Facilities

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

Direct Costs:

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

- **Travel:** Include costs to be incurred by DoD civilian and military personnel. However, **note that these costs cannot be reimbursed through the extramural award.** They can only be funded directly by the Federal Government to the facility. Some restrictions apply. Processes will be discussed during negotiations.

- **Consultants, Equipment, Materials, Supplies, Other, Etc.:** Include all anticipated direct costs. The Military Facility should consider whether the applicant organization can purchase the items/resources and provide them to the facility. The organization may provide resources to the Military Facility, such as consultants, supplies, equipment, etc., acquired with award funds. If this is feasible, these funds should be included on the applicant organization's Research & Related Budget Form and should not be included on this form. Title of all equipment will remain with the Government.

- **Rates/Fees (Other than Indirect Cost Rates and Profit):** Where there are no DoD-established reimbursement rates (e.g., Institutional Review Board [IRB] 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 RM office (or equivalent) for assistance in determining a rate.

- **Total Costs:** Include the facility's combined direct and indirect costs. Enter the total here and also include it in the Subaward/Consortium/Contractual Costs budget line on the Research & Related Budget Form (Section F.5).

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

when performing collaborative research with the extramural organization must meet the requirements of the DoD's Financial Management Regulation (FMR) 7000.14-R.

Direct Fund by Federal Agency: The USSCOM's RM office will "direct fund" (via a Funding Authorization Document [FAD], Military Interdepartmental Purchase Request [MIPR], 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.

Technology Transfer: The Military Facility researcher(s) should also coordinate with his/her technology transfer office, when applicable. The facility may require that a Cooperative Research and Development Agreement (CRADA) or other instrument (as authorized by law or regulation) be executed between the facility and the 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 submission. A timeline for execution of the document will be established during negotiations.

B. Submission of a Grants.gov Workspace

An application must be submitted through Workspace by clicking the "Sign and Submit" button on the Manage Workspace page, under the "Forms" tab. 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 applications must be received by the deadline indicated on the title page of the respective BAA. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the 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 their application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of their timely submission.

C. Applicant Verification of Grants.gov Submission in eBRAP

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

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

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific 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 application components and ensure proper ordering as specified in the BAA. ***If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline. The full application submission deadline and the end of the application verification period in eBRAP are stated in the specific BAA.

D. 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 the 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 changes to DoD compliance requirements (Department of the Army Pamphlet [DA PAM] 385-69, DA PAM 385-10, 32 CFR 651, 6 September 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

Use of Human Subjects, Human Anatomical Substances, Human Subject Data, Human Cadavers, and Animals

The USAMRDC Office of Human Research Oversight (OHRO)and USSOCOM's Veterinarian Review Office (VRO) ensures that research conducted, contracted, sponsored, supported, or managed by the DoD and involving human subjects, human anatomical substances, human subject data, human cadavers, and animals are conducted in accordance with Federal, DoD, Army, USAMRDC, USSOCOM, and international regulatory requirements.

PIs and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until regulatory documents are submitted and approved by the USAMRDC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, "USE OF ANIMALS IN DOD CONDUCTED AND SUPPORTED RESEARCH AND TRAINING," as issued March 20, 2019, available at https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321601p.pdf and DoDI 3216.02, "PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-CONDUCTED AND -SUPPORTED RESEARCH," as issued on April 15, 2020 with Change 1 Effective June 29, 2022, and available at www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

The USSOCOM Veterinarian Review Office (VRO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The Office of Human Research Oversight (OHRO)is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human subject data and/or***

specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI's institution as well as a determination from the Office of Human Research Oversight (OHRO) at USAMRDC. A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested **if the proposal is selected for funding**. The USSOCOM VRO, must review and approve all animal use prior to the start of working with animals. All amendments or modifications must also be reviewed prior to initiation for the life of the award. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a "VRO_Animal Research_Review". The VRO review documents can be found on the USSOCOM Research Protections website at:

https://www.socom.mil/SOF-ATL/Pages/HRPO.aspx

Allow at least 1 to 2 months for regulatory review and approval processes for animal studies.

For additional information, send questions via email to VRO (socom_vet@socom.mil).

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

Research, development, test and evaluation (RDT&E), education or training activities involving human cadavers or human anatomical substances obtained from cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training, November 05 2019 (https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo). The USAMRDC OHRO is the Action Office (usarmy.detrick.medcom-USAMRMC.other.hrpo@health.mil) for this policy. **OHRO must review the use of postmortem specimens for compliance with the Army Cadaver Use Policy.** Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the awardee. Questions regarding submission of human cadaver research for USAMRDC OHRO review and approval should be directed to the OHRO at usarmy.detrick.medcom-USAMRMC.other.hrpo@health.mil.

3. Research Involving the Secondary Use of Data/Specimens

All USSOCOM-supported research involving the secondary use of human data, records, human tissue, or human specimens (hereafter referred as data/specimens) must be reviewed for compliance with Federal and DoD human subjects protection requirements and approved by the USAMRDC ORP prior to implementation. USAMRDC OHRO review includes assessing the source of the data/specimens and whether the initial manner and consent for the data/specimen collection permits use in the DoD-funded research protocol. OHRO review, approvals, and determinations for specimen research are based upon the nature of the research, the source of the data/
specimens, use and/or disclosure of identifiable health information, privacy and confidentiality protections, and whether the individual providing the data/specimens allowed the use of his/her data/specimens for research. For additional guidance and instructions on OHRO review of any

DoD-funded research activities involving access, use, and analysis of data/specimens, investigators should submit the OHRO Submission Form for Secondary research found on the OHRO website. https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

4. **Research Involving Human Subjects**

In addition to local IRB review, investigators must submit all USSOCOM-funded research protocols involving human subjects for review and approval by the USAMRDC OHRO prior to implementation of the research. The focus of this review is to validate the IRB review as appropriate and ensure that DoD, Army, and USAMRDC and USSOCOM regulatory requirements have been met.

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

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

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

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

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

Specific requirements for HRPO submission and review of research involving human subjects can be found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

(1) Assurance of Compliance: Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection (OHRP) Federal Wide Assurance (FWA) or DoD Assurance.

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

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

- A statement that the U.S. DoD is providing funding for the study.
- A statement that representatives of the DoD are authorized to review research records.
- In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.

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

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

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

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

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

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;

- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- Overseeing data matching, data collection, and analysis.

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

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

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

1. **Military Personnel Volunteers:** The following is important information for research projects proposing to include military personnel as volunteers.
   - **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with Service-specific requirements.

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

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

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

recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.
- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

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

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo.

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

C. Clinical Trial Registry

PIs are required to register clinical trials individually on https://clinicaltrials.gov/ using a Secondary Protocol ID number designation of "CDMRP-eBRAP Log Number" (e.g., CDMRP-BA23####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated "CDMRP-eBRAP Log Number-A, B, C, etc." (e.g., CDMRP-BA23####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see http://prsinfo.clinicaltrials.gov/, click on "Support Materials (including data element definitions)") are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

D. Research Involving Recombinant DNA Molecules

The awardee assures that all work involving the use of recombinant DNA will be in compliance with guidance provided at https://osp.od.nih.gov/biotechnology/nih-guidelines/.

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:

- Technical/Scientific:
  - Monthly, quarterly, and/or annual progress reports
  - Final progress report
  - In-progress reviews
  - Quad charts: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/ProgramFY.htm?programFYId=513103 and completed for submission and application.

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 with 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. Questions related to OHRO review requirements should be directed to the OHRO mailbox at usarmy.detrick.medcom-USAMRMC.other.hrpo@health.mil.
  - Research Involving Animals: Questions concerning animal use and review should be directed to the USSOCOM VRO:

    Phone: 813-826-6548
    Email: socom_vet@socom.mil

B. Disclosure of Proprietary Information

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

Proprietary information submitted in a proposal may be disclosed outside the Government for the sole purpose of evaluation. Evaluators must agree that proprietary information in the proposal will be used for evaluation purposes only and will not be further disclosed or used. All proposal may be subject to public release under the FOIA.

Proposals for funded projects will be subject to public release under the FOIA to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

C. Marking of Proprietary Information

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

D. Award Notices

Awards are made to organizations, not to individual PIs. The requiring activity executes its extramural research program primarily through the award of contracts. Any resultant award from this BAA will be issued as a research and development contract that will adhere to the FAR. Please familiarize yourself with the FAR at https://acquisition.gov/far/.

A procurement contract is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) supplies or services for the direct benefit or use of the U.S. Government (31 USC 6303). The contract type, along with the start date, will be determined during the negotiation process. After email notification that proposal review results can be found on eBRAP, and if the proposal 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 Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Contracting is the official authorizing document.

E. Inquiry Review

If an application is not recommended for funding, the organization or PI may submit an inquiry within 15 business days after the notification email is sent. Inquiries submitted after 15 business days will not be considered.

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

Inquiries in response to funding recommendations should be submitted to the USAMRAA Contracting Officers through the eBRAP Help Desk at help@eBRAP.org.

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.

F. Information Service

Applicants may use the technical reference facilities of Defense Technical Information Center (DTIC). DTIC or the National Technical Information Service (NTIS) to acquire information regarding existing research to avoid duplication of scientific and engineering effort. The DTIC physical address is 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218; the website is http://www.dtic.mil; and the telephone number is 800-225-3842. NTIS is located at 5285 Port Royal Road, Springfield, VA 22161; the website is www.ntis.gov; and the telephone number is 703-605-6000.

G. Freedom of Information Act Requests

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

When an FOIA request asks for information contained in a successful proposal 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 USAMRAA 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 USAMRAA's intent to release and will be provided a reasonable opportunity to assert available action.

H. 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 the following disclaimer: "Any

opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the (name of contracting agency(ies))."

"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, through the (*insert program name*) under Award No. (HT9425-23-X-XXXX). Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of 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." (http://www.nih.gov)

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

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

I. Contracted Fundamental Research

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. It is at US Government discretion to fund research with Budget Activity 3 or higher funds 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.

J. Sharing of Proposal Information

The USSOCOM shares proposal information with other Federal funding agencies (e.g., NIH, National Science Foundation, Department of Veterans Affairs) to inform funding priorities and decisions, and to increase transparency. By sharing and leveraging this information, duplication of efforts can be avoided, allowing for the support of more investigators with Federal funds. The USSOCOM believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on USSOCOM-funded awards including awardee information and published results are shared on DTIC. Additional information on DTIC can be found at https://discover.dtic.mil/

K. Data Management and Sharing

Purpose

Data sharing enables researchers to rigorously test the validity of research findings, strengthen analyses through combined datasets, reuse hard-to-generate data, and explore new frontiers of discovery. In addition, USSOCOM emphasizes the importance of good data management practices, which provide the foundation for effective data sharing and improve the reproducibility and reliability of research findings. USSOCOM encourages data management and data sharing practices consistent with the FAIR data principles (https://www.go-fair.org/fair-principles/)

USSOCOM expects researchers and institutions to implement data management and sharing practices as described.

Definitions

For the purposes of this BAA, terms are defined as follows:

Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.

Data Management: The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

Data Sharing: The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.

Metadata: Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

Scope

This guidance applies to all research, funded or conducted in whole or in part by USSOCOM, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, Intramural Research Projects, or other funding agreements regardless of USSOCOM funding level or funding mechanism. This

guidance does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.

Managing and Sharing Scientific Data

USSOCOM expects that in drafting Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Any potential limitations on subsequent data use should be communicated to individuals or entities (e.g., data repository managers) that will preserve and share the scientific data.

Considerations for Scientific Data Derived from Human Participants: USSOCOM prioritizes the responsible management and sharing of scientific data derived from human participants. Applicable federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies govern research involving human participants and the sharing and use of scientific data derived from human participants. USSOCOM also respects Tribal sovereignty in the absence of written Tribal laws or polices. This USSOCOM guidance is consistent with federal regulations for the protection of human research participants and other USSOCOM expectations for the use and sharing of scientific data derived from human participants, including the NIH's 2014 Genomic Data Sharing (GDS) Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) 2015 Intramural Research Program Human Data Sharing Policy (https://policymanual.nih.gov/3016), and 45 CFR 46 (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). Researchers proposing to generate scientific data derived from human participants should outline in their Plans how privacy, rights, and confidentiality of human research participants will be protected (i.e., through de-identification, Certificates of Confidentiality (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html), and other protective measures).

USSOCOM strongly encourages researchers to plan for how data management and sharing will be addressed in the informed consent process, including communicating with prospective participants how their scientific data are expected to be used and shared. Researchers should consider whether access to scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled.

Data Repository Selection: USSOCOM strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data. The Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research (https://sharing.nih.gov/data-management-and-sharing-policy/sharing-scientific-data/selecting-a-data-repository) assists researchers in selecting a suitable data repository(ies) or cloud-computing platform.

Data Preservation and Sharing Timelines: Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Researchers are encouraged to consider

relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend. 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: If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (https://fitbir.nih.gov/content/policies-and-procedures).

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

- Systems Biology: If the project includes systems biology (SB)-related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (https://sysbiocube-abcc.ncifcrf.gov/).

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

L. Property/Equipment

Contracts: Reference FAR Part 45 and DFARS Part 245.

M. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), the contractor/recipient and collaborators may elect to retain title to their subject inventions and technical data, subject to meeting the reporting and patent filing requirements and retained rights to the Federal Government. The Federal Government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed. The FAR and 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

N. PI Changes and Award Transfers

Transfer of a Contract Award to New Organization: Unless restricted by the specific BAA, a change in organizational affiliation will be considered on a case-by-case basis by the USAMRAA Contacting Officer. If approved, the PI's original organization will be required to

agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a study site/clinical trial at its location.

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

APPENDIX 3

QUALIFICATION INFORMATION

A. Contractor/Recipient Qualification

The USAMRAA 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/portal. The USAMRAA also reviews and considers information about the applicant in the Office of Management and Budget (OMB)-designated integrity and performance system, currently the SAM.gov Responsibility/ Qualification (R/Q), prior to making an award, as described in the BAA, Section II.E.5.

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 R/Q. The recipient may submit comments to R/Q about any information that the Federal awarding agency reported to R/Q, 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 R/Q about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent five-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually the information about the criminal, civil, and administrative proceedings that Section 872(c) describes. Reference Federal Register Notice, Vol. 80, No. 140, Wednesday, July 22, 2015. In addition, per NDAA 2021 Section 1062, beginning October 1, 2023, DoD may not fund institutions of higher education (as defined by 20 USC 1002) that host a Confucius Institute, other than amounts provided directly to students as education assistance, unless a waiver is provided. A Confucius Institute is defined as a cultural institute directly or indirectly funded by the Government of the People's of Republic of China

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 do not overlap with their fully funded intramural programs. Such agencies are required to explain how their proposals do not overlap with their intramural programs.

C. J-1 Visa Waiver

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

Note: The Federal Government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (http://www.state.gov/j/ct/list/c14151.htm). Additional information on J-1 Visa Waivers can be located at the following Department of State website: travel.state.gov/visa/temp.

D. Conflict of Interest

1. Contract Awards

Organizational and Consultant (individual) Conflicts of Interest: Contracts must comply with the requirements found in FAR 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 9.5 will be used as a guide in analyzing and resolving organizational and consultant COIs relating to an award.

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

2. 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 discussed with the USSOCOM legal staff at (813) 826-9919, prior to expending time and effort in preparation of a proposal.

APPENDIX 4

FORMATTING GUIDELINES

All Pre-proposal and proposal 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 forms must be uploaded as an individual file in the format specified in the BAA. All contributors to the proposal must use matching compatible versions of Adobe software for all PDF documents when editing and preparing proposal 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 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 directing reviewers to websites that contain additional information about the proposed research are not allowed in the proposal 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 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.usamraa.army.mil/Pages/Resources.aspx. 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 SF424 (R&R) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

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

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

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

All applicants are required to complete the representations below and submit with each proposal. The form for completion and submission is posted in eBRAP (https://ebrap.org/eBRAP/public/Program.htm) under the Organizational Forms Section, document titled "Required Representations". 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 submission, the applicant organization represents that it:

(1) Is ___ is not _____ a Corporation ("Corporation" means any entity, including any institution of higher education, other nonprofit 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 (R&R) (Attachment 01) , 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, 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 Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

National Policy Requirements

The awardee must comply with the following requirements, as applicable. Full text of National Policy Requirements is available at https://www.usamraa.army.mil/Pages/Resources.aspx. 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

APPENDIX 6

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
BAA	Broad Agency Announcement
CAGE	Commercial and Government Entity
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
CMR	Contractor Manpower Reporting
COI	Conflict of Interest
COR	Contracting Officer's Representative
CRADA	Cooperative Research and Development Agreement
DA PAM	Department of the Army Pamphlet
DCAA	Defense Contract Audit Agency
DFARS	Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDI	Department of Defense Instruction
DTIC	Defense Technical Information Center
eBRAP	Electronic Biomedical Research Application Portal
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAD	Funding Authorization Document
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FMR	Financial Management Regulation
FOA	Funding Opportunity Announcement
FOIA	Freedom of Information Act
FR	Federal Register
FWA	Federalwide Assurance
FY	Fiscal Year
G&A	General and Administrative
GOR	Grant Officer's Representative
GSA	General Services Administration
HIPAA	Health Information Portability and Accountability Act
HRPO	Human Research Protection Official
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board

JPEG	Joint Photographic Experts Group
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health
OHRO	Office for Human Research Oversight
OMB	Office of Management and Budget
ONR	Office of Naval Research
ORCID	Open Researcher and Contributor Identification
ORP	Office of Research Protections
PARC	Principal Assistant Responsible for Contracting
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
R/Q	Sam.Gov Responsibility/Qualification
R&R	Research and Related
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SB	Systems Biology
SF	Standard Form
SFLLL	Standard Form LLL
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
UEI	Unique Entity Identifier
UPIRTSO	Unanticipated Problems Involving Risk to Subjects or Others
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USSOCOM	United States Special Operations Command
USC	United States Code
VRO	Veterinarian Review Office
WAV	Waveform Audio