

General Submission Instructions

Broad Agency Announcement for Medical Research

Fiscal Year 2018 – Fiscal Year 2022

Department of Defense
U.S. Army Medical Research and Development Command

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This General Submission Instructions document must be read in conjunction with the broad agency announcement, available for downloading from [Grants.gov](https://www.Grants.gov).

I. HELPFUL INFORMATION

A. Tips for Success



This symbol marks helpful hints throughout this document.



This symbol refers to the Funding Opportunity Announcement/broad agency announcement (BAA) for specific instructions.

B. Current Funding Opportunity Announcement

The Fiscal Year 2018 – Fiscal Year 2022 (FY18 – FY22) U.S. Army Medical Research and Development Command's (USAMRDC) BAA can be found by searching Grants.gov (<http://www.grants.gov/>) using the Funding Opportunity Number **W81XWH-18-S-BAA1** or the Assistance Listing (AL) Number **12.420 Military Medical Research and Development**.

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

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

C. Receiving Emails from eBRAP and Grants.gov

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

On occasion, the Grants.gov proposal/application package (hereinafter, submission package) may be updated or changed. The applicant must use the latest version of the Grants.gov submission package; proposals/applications submitted with a different version of the Grants.gov submission package will be rejected by Grants.gov. Applicants are encouraged to sign up to receive notifications of any changes to the funding opportunity (<https://www.grants.gov/>) through either (1) the "Send me change notification emails" link on the Synopsis page for the BAA or (2) by responding to the Grants.gov prompt *when first downloading the Grants.gov proposal/application package* (extramural applicants only).

D. Agency Contacts

1. **eBRAP Help Desk:** Questions related to BAA content or submission requirements, as well as questions related to submission of pre-proposals/pre-applications through eBRAP, should be directed to the Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time. Response times may vary depending upon the volume of inquiries. Be

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

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

Email: support@grants.gov

II. REGISTRATION AND SUBMISSION INFORMATION

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



Submission of proposals/applications from U.S. federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. See [Section III.A.5, Research & Related Budget](#).



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

A. eBRAP Registration

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



eBRAP does not confirm the accuracy of file content!

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

PIs with an Open Researcher and Contributor ID (ORCID) identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

During eBRAP registration, the PI must request to be affiliated with their 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/pre-application to be submitted. ***However, before the full proposal/application submission deadline, the organization’s eBRAP registration must be complete to allow for processing, viewing, and modifying of the Grants.gov submission package components.***

The Application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be identical between the pre-proposal/pre-application and the full proposal/application for eBRAP to process a proposal/application. Mismatched information may delay the availability of the proposal/application during the proposal/application verification period. For the PI to view/modify files, the PI’s name and email address in the eBRAP pre-proposal/pre-application submission must match the information provided in Standard Form 424 (SF424) Research & Related (R&R) 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/pre-application submission must match the information provided in SF424 (R&R) of the Grants.gov submission package.

B. Submission Dates and Times

This BAA is continuously open for a 5-year period, from October 1, 2017, through September 30, 2022. **Pre-proposals/pre-applications are required** and may be submitted at any time throughout the 5-year period.

The Grants.gov Program Management Office schedules regular system-wide downtimes to deploy new software releases and perform system maintenance. A schedule of the anticipated dates can be found at <https://www.grants.gov/web/grants/support/calendar.html>. During these times, Grants.gov will be unavailable. Applicants are encouraged to plan their submissions accordingly.

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



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

During pre-proposal/pre-application submission, the PI must identify a Business Official from the list of Business Officials registered with eBRAP. If the PI’s Business Official is not already registered with eBRAP, the PI must invite the Business Official to register. ***The Business Official’s registration must be completed prior to the full proposal/application deadline to allow the Business Official to view/modify the full proposal/application files in eBRAP after submission.***

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

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

Tab 1 – Application Information: Enter the information as described in eBRAP before continuing the pre-proposal/pre-application. Click on “Save.” 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>. The codes have been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

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 (R&R) in the Grants.gov package). ***The Business Official must be either selected from the eBRAP list or invited in order for the pre-proposal/pre-application to be submitted.***

If the organization’s Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. 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 [R&R]), and click on “Add Organizations to this Pre-application.”

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

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

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

If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable; however, those Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.

To preserve the integrity of its peer and programmatic review processes, the USAMRDC discourages inclusion of any employee of its review contractors in proposals/applications for funding. For FY18 – FY22, the peer review contractor is General Dynamics Information Technology, Inc. The programmatic review contractor may vary. Proposals/applications 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: To avoid COIs during the screening and review processes, list all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship). Click on “Save.”

Tab 5 – Pre-Application Files: Upload all documents as PDF as specified in the BAA. Documents should conform to the formatting guidelines outlined in [Appendix 4](#). Click on “Upload.”

- eBRAP will truncate characters exceeding the limit specified for each data field as specified in the BAA.
- 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-Application: Enter eBRAP password and click the “Submit” button. Click the “Confirm Submission” button to complete the pre- proposal/pre-application submission. *This finalizes the pre-proposal/pre-application process.*



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

Following completion of pre-proposal/pre-application submission, the status of the pre-proposal/pre-application in eBRAP will change from “DRAFT” to “SUBMITTED,” and a confirmation email will be sent to the PI and named Business Official. *A pre-proposal/ pre-application in DRAFT status will not be forwarded for review.*

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

A PI must be invited to submit a full proposal/application. An invited full proposal/application must be submitted electronically through a Grants.gov Workspace (<https://www.grants.gov>). Proposals/applications 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 a proposal/application. Applicants must create a Workspace, invite

grant team members to join the Workspace, complete the required forms, and submit their proposal/application Workspace package.

To apply through Grants.gov, an organization must complete the Grants.gov registration process.
Allow up to 8 weeks for the completion of the Grants.gov registration process.

No allowances/exceptions will be made to submission deadlines due to submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.
Registering early is advised.

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/application verification period.

It is the applicant's responsibility to verify their 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>.
Resubmission of a proposal/application 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 Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management (SAM).

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

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

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an "Active" status before submitting an application through Grants.gov. As published in the Federal Register 10 July 2019 (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the Unique Entity Identifier for awards management generated through SAM will replace the Data Universal Numbering System (DUNS) number as of April 2022. ***All federal awards including but not limited to contracts, grants, and cooperative agreements will use the Unique Entity Identifier (termed "SAM").*** The DUNS will be phased out as the identifier within SAM between July 2019 and April 2022. Until 4 April 2022, the DUNS number remains the official identifier. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new Unique Entity Identifier displayed in SAM. For more information, visit General Services Administration (GSA): <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>.

Current SAM.gov registrants are assigned their Unique Entity Identifier and can view it within SAM.gov.

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 application submission deadline.*** An organization can register in SAM online at <https://www.sam.gov/SAM/>. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination to direct the federal award to a qualified applicant.

Additional information and step-by-step registration directions are detailed in the SAM User Guide and other GSA training materials in the Help area at <https://www.sam.gov/SAM/>.

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

2. Commercial and Government Entity Code

The applicant organization must have a Commercial and Government Entity (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 code). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by visiting the website (<https://cage.dla.mil/Home/UsageAgree>). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

3. Authorized Organizational Representative

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

An AOR must first register with the Grants.gov credential provider at <https://apply07.grants.gov/apply/OrcRegister> to obtain a username and password. Once an AOR has completed the Grants.gov registration process, Grants.gov will notify the E-Biz POC of the registration. The E-Biz POC will then log in to Grants.gov and assign and authorize the appropriate roles, which may include the AOR

role, thereby giving the AOR permission to complete and submit proposals/applications on behalf of the organization. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

At the time of proposal/application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the proposal/application is current, accurate, and complete.

When proposals/applications are submitted through Grants.gov, the name of the organization's AOR that submitted the proposal/application is inserted into the signature line of the proposal/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.***

4. Grants.gov Workspace

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

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

Applicants who prepare the application outside the Workspace must download the individual PDF forms from Grants.gov, complete and save the forms, and upload 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/applications must be resubmitted using a new Grants.gov submission package and a supported version of Adobe Reader prior to the proposal/application submission deadline. It is the applicant's responsibility to verify 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/othereversions/>. All contributors to the proposal/application must use matching compatible versions of Adobe software when editing and preparing proposal/application components outside the Workspace. The use of different software versions will result in corruption of the submitted file.

No allowances/exceptions will be made to submission deadlines due to submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Any modifications to the Project Narrative or Budget Form require submission of a changed/corrected Grants.gov submission package to Grants.gov prior to the proposal/application submission deadline.

A. Grants.gov Submission Package Components for Research Proposals/Applications

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

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

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

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

Block 4a – Federal Identifier Box. Enter in your eBRAP log number assigned during pre-proposal/pre-application submission.

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

4. a. Federal Identifier	
b. Agency Routing Identifier	
c. Previous Grants.gov Tracking ID	

- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/corrected proposals/applications, enter the Grants.gov tracking number for the original proposal/application.
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. “Person to be contacted on matters involving this application” is the Business Official.
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue Service. If applying from an organization outside the United States, enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select “New” for all submissions.

- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant’s Project.** Enter the same project title as used for the pre-proposal/pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the proposal/application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the proposal/application. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option b., “NO, program is not covered by E.O. 12372.”

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

- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL (SFLLL) to disclose lobbying activities pursuant to 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 Research & Related Application for Federal Assistance Form prior to the full proposal/application submission deadline.

2. Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form. Following retrieval and processing of the Grants.gov proposal/application, eBRAP will notify the organizational representatives and PI by email to log into the eBRAP to view, modify, and verify the Grants.gov proposal/application submission. eBRAP will validate retrieved files against the BAA guidelines, and 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/application components and ensure proper ordering as specified in the BAA. See [Section III.C, Applicant Verification of Grants.gov Submission in eBRAP](#), for additional details.

Each attachment in the Attachment Form must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in [Appendix 4](#). For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed

20 MB and the file size for the entire 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: Upload as a PDF named “ProjectNarrative.pdf”. The Project Narrative is the main body of the proposal/application. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, 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/application. There is no form for this information. A detailed description of the research to be undertaken should be submitted. This should include the areas described in the BAA.

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

Attachment 2: Supporting Documentation: Combine and upload as a **single PDF file named “Support.pdf”**. Include only supporting documentation as indicated in the BAA. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the proposal/application may be administratively withdrawn. ***The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the proposal/application.***



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

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

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

The Technical Abstract will be posted publicly and will be included in the award agreement. Do not include proprietary information.

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

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

Attachment 5: Statement of Work (SOW): Upload as a PDF named “SOW.pdf”. The SOW outlines and establishes the performance expectations and milestones for which USAMRDC may provide funding. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under Freedom of Information Act (FOIA).

SOW Format: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. *The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>).*

The SOW must be in PDF format prior to attaching. The government reserves the right to request a revised SOW format and/or additional information.

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

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); description of research with animals, human anatomical substances, and/or human subjects or cadavers to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. As applicable, estimated times to complete each task should include time for local and USAMRDC regulatory review and approval, as shown below. Refer to [Appendix 1](#) for additional information regarding regulatory review.
 - For studies involving human subjects, include a subtask that allows at least 2 to 3 months for regulatory review and approval by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO); this does not include the additional time required for local Institutional Review Board (IRB) review and approval.
 - For animal studies, include a subtask that allows at least 3 to 4 months for regulatory review and approval by the USAMRDC Animal Care and Use Review Office (ACURO); this does not include the additional time required for local Institutional Animal Care and Use Committee (IACUC) review and approval.

Attachments 6-15: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the BAA (e.g., “Impact.pdf,” “Transition.pdf,” etc.).



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

3. Research & Related Personal Data

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

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

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

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

Figure 2. PI’s eBRAP User Name

PROFILE - Project Director/Principal Investigator

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

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 research support,*** include the title, time commitments, supporting agency, name and address of the funding agency’s procuring Contracting/Grants Officer, period of performance , level of funding, brief description of the project’s goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.
 - 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, irrespective of 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, laboratory space, scientific materials, selection to a foreign “talents” or similar-type program, or other foreign or domestic support must be reported.
 - 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.

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

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

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (U.S. Code, Title 18, Section 1001).

5. Research & Related Budget

An estimate of the total proposed research project costs, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget form. For limits on funding amounts, types of costs, and period of performance, refer to the program announcement. The budget and budget justification should include sufficient detail for each year so that the government can determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. ***The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.*** At the time of proposal/application submission to Grants.gov, the AOR is certifying to the best of 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/application submission deadline. No budget will be approved by the government exceeding the cost limit stated in the specific program announcement or using an indirect rate exceeding the organization’s negotiated rate.

Budget Regulations and Restrictions:

The following must be utilized in developing the budget:

- **Administrative and Cost Principles.** Awardees are required to comply with the following, as applicable:
 - Federal Acquisition Regulation (FAR) Part 31
 - Defense Federal Acquisition Regulation Supplement Part (DFARS) 231
 - Provisions of Chapter I, Subchapter C of Title 32, Code of Federal Regulations, “DoD Grant and Agreement Regulations,” Parts 26, 28, 34, 37, and 1125 (32 CFR 26, 28, 34, 37, and 1125)
 - 2 CFR Part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,” implemented by Chapter XI of 2 CFR
- **Award Funding/Maximum Obligation:**
 - Contract Awards: Reference contract funding regulations in FAR Part 32.7 and DFARS Subpart 232.7.
 - Assistance Agreement Awards: Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Pre-Award Costs:** Pre-award costs may be allowable as follows:
 - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. An advanced agreement must be executed by the Contracting Officer prior to incurring any cost. Advanced Agreement Costs (Pre- Contract Costs) are referenced in FAR 31.205-32 and Advanced Agreements in FAR 31.109.
 - **Assistance Agreement Awards:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the federal government’s prior approval, incur obligations and expenditures to cover costs up to 90 days before the start date of the period of performance, if such costs (1) are necessary to conduct the project; and (2) would be allowable under the award, if awarded, without the government’s prior approval. If specific expenditures would otherwise require prior approval, the awardee must obtain the Grants Officer’s approval before incurring the costs. Government prior approval is required for any costs to be incurred more than 90 days before the start date of the period of performance. For-profit organizations must obtain the Grants Officer’s approval prior to incurring any obligations and expenditures before the start date of the period of performance. Reference 2 CFR 200.458.

For-profit organizations must obtain the Grants Officer’s approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award. Reference 32 CFR 34.15.

The incurrence of pre-award costs in anticipation of an award imposes no obligation on the government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award

costs incurred. The federal government expects the awardee to be fully aware that pre-award costs may result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives in the approved timeframe or in any way adversely affect the conduct of the project.

- **Cost of Preparing Proposals/Applications:** The cost of preparing proposals/ applications in response to the BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals/applications may be an allowable expense included in the indirect/ facilities and administrative cost as specified in the organization's applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the 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/application. For all federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.***

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

For Collaborating Military Facilities: A proposal/application from an extramural organization that includes collaboration with a Military Facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) must submit a DOD Military Budget as instructed in [Section 8, Suggested Collaborating DOD Military Facility Budget Format](#), below. The costs per year should be included on the Grants.gov Research & Related Budget form under subaward costs.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the Research & Related 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.***
- **Level of Effort (Calendar, Academic, and Summer Months):** For each senior/key person, including unpaid personnel, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the proposal/application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed. Describe 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.
- **Level of Effort (Calendar, Academic, and Summer Months):** For each project role category, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most federal agencies, funding cannot be applied toward federal salaries; therefore, these salaries should not be included in the requested budget.***
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the proposal/application is recommended for

funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).

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

Section C: Equipment Description: Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per-unit acquisition cost that equals or exceeds the lesser of (1) \$5,000 or more per unit, or (2) the awardee's or subawardees' capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

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

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

Section D: Travel: Travel costs may include:

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

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

Section F: Other Direct Costs

- **Materials and Supplies:** 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, 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 & Related Budget form under subaward costs.



All direct and indirect costs of any subaward must be included in the direct costs of the primary award. No budget will be approved by the government exceeding the indirect rate exceeding the organization’s negotiated rate.

- **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
- **Alterations and Renovations:** Alteration and renovation costs can be requested if the costs are essential to accomplish the objectives of the research project and **are a minor portion of the overall budget**. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. **Costs for the construction of facilities are not allowable.**
- **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization’s current cost/rate schedule.

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

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

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://rates.psc.gov/fms/dca/negotiations.html>), the ONR (<https://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx>), and the DCAA (<https://www.dcaa.mil>) for additional information on indirect rates.

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

Section J: Fee: Charging a fee or profit to an assistance agreement, either by the recipient/awardee, subrecipient/subawardee is prohibited. For contracts, 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/applications from **federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.



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

6. Project/Performance Site Location(s) Form

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

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

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

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 Suggested Collaborating DOD Military Facility Budget Format (Section 8, below).

8. Suggested Collaborating DOD Military Facility Budget Format

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

Budget Form: Complete a separate “**Suggested Collaborating DOD Military Facility Budget Format**,” 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 Research & Related Subaward Budget Attachment Form.

Direct Costs:

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

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

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

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

Funds Obligated on Extramural Award: If extraordinary circumstances exist whereby the USAMRDC RM office is not able to "direct fund" the Military Facility, the funds may be placed on the award and the awardee may provide award funds to the Military Facility. If known at the time of submission, the Military Facility, in conjunction with the applicant organization, should provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility and the associated costs, when the activities will take place, why "direct funding" is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc.

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

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

B. Submission of a Grants.gov Workspace

A proposal/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 proposals/applications must be received by the deadline indicated on the title page of the BAA. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the proposal/application is successfully received by Grants.gov. The applicant AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of their proposal/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 proposal/application package submitted to Grants.gov may be viewed in eBRAP until the end of the proposal/application verification period. After eBRAP has processed the full proposal/application, PIs will receive an email notification of this status and will be able to view and modify proposal/application components in eBRAP. During the proposal/application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Research & Related Budget Form***, may be modified. See the BAA for specific full proposal/application submission and proposal/application verification deadlines.

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

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

D. Proposal/Application Tracking

After a Workspace package has been successfully submitted, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission. Participants can also find the Grants.gov Tracking Number on the Manage Workspace page, under the “Details” tab. The submission of a Workspace package can be tracked from 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 recent 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://mrhc.amedd.army.mil/index.cfm/resources/researcher_resources/safety.

B. Research Protections Review Requirements

All DOD-funded investigators must submit research protocols involving new and ongoing research with human anatomical substances, human subjects, human cadavers, or animals must be reviewed and approved by the USAMRDC Office of Research Protections (ORP) for review and approval prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB), Ethics Committee (EC) review, or Institutional Animal Care and Use Committee (IACUC) review. PIs and applicant organizations may not commence performance of research involving the above, or expend funding on such efforts, until receipt of written approval by the USAMRDC ORP.

The USAMRDC ORP conducts site visits as part of its responsibility for compliance oversight. Investigators must make accurate and complete study records available to representatives of the USAMRDC as a part of their responsibility to protect human subjects in research. Research reports must be stored in a confidential manner to protect the confidentiality of subject information.

All ORP expectations are consistent with the DoD Instruction (DoDI) 3216.01, "Use of Animals in DoD Programs," available at

https://mrhc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro/regulations and DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," and available at <https://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

1. Research Involving Human Subjects or Human Anatomical Substances

The ORP Human Research Protection Office (HRPO) compliance with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DOD. **Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.** Allow additional time for research taking place in international settings.

The research protocol submitted for review must include only those activities funded by the DOD, as referenced in the approved Statement of Work. The HRPO will not review protocols submitted for DOD-funded activities if such studies have been added to an ongoing/existing protocol.

Effective 20 January 2020, any institution located in the U.S. that is engaged in multi-site cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the U.S. The primary awardee (lead institution) of a USAMRDC-managed research proposal that includes a multi-site, cooperative effort must develop a plan for coordinating all collaborating sites' reliance on a single IRB for DoD-supported multi-site cooperative research.

For investigator guidance and HRPO submission toolkit, please see the HRPO website at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo.

Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in the Statement of Work attachment. Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones.

2. Research Involving Animal Use

The ORP's Animal Care and Use Review Office (ACURO) will request specific documents relating to the use of animals in the proposed research will be requested **if the proposal/application is selected for funding**. The ACURO, a component of the USAMRDC ORP, must review and approve all animal use prior to the start of working with animals. All amendments or modifications must also be reviewed prior to initiation for the life of the award. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, "Research Involving Animals." For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro/animal_appendix. *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*

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

3. 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 ORP approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, April 20, 2012 (https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections). The USAMRDC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. **HRPO 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. ORP will issue written approvals to begin the activity under separate notification to the awardee. Investigators may direct questions regarding submission of human cadaver research for USAMRDC ORP review and approval at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

4. Research Involving the Secondary Use of Data/Specimens

For all DOD-funded research involving the use of human data and/or specimens the investigator must secure an institutional determination letter (e.g., stating that the project does not constitute research involving human subjects or exempt human subjects research) from the PI's human subjects protection office as well as a concurrence from the ORP HRPO that research may proceed. For DOD-funded research activities involving access, use, and analysis of data/specimens, investigators should submit the HRPO Submission Form for Secondary Research found on the ORP HRPO website (https://mrdd.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo).

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- BA18#####). 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- BA18#####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see <https://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. PIs conducting phase 3 clinical trials shall submit results of analyses of group differences on the basis of sex/gender, race, and/or ethnicity to clinicaltrials.gov at the time of final report submission. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

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:

- Contractor Manpower Reporting (CMR):
 - CMR is now a requirement of all DOD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal/application for providing this data. A “nominal fee” is defined as a computation of an administrative assistant-equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal/application cost/price.
 - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to report the information outlined in FAR 52.204-14 or FAR 52.204-15, for services performed during the preceding government fiscal year under the contract or order that exceed the thresholds established in FAR 4.1703(a)(2), using the following web address: <https://www.sam.gov/SAM>.
 - Reporting input will be for the labor executed during the period of performance during each government fiscal year, which runs October 1 through September 30. While input may be reported any time during the fiscal year, all data shall be reported no later than October 31 of each calendar year.
- Technical/Scientific:
 - Monthly, quarterly, and/or annual progress reports, as indicated in the Terms and Conditions of the award
 - Final progress report
 - In-progress reviews
 - Quad charts: The Quad Chart template is a one-page Word document or PowerPoint file that must be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm> and completed for submission.

USAMRDC research progress reporting requirements and instructions can be found at https://mrhc.amedd.army.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 HRPO requires prompt submission of institutional continuing review reports, study events, and substantive protocol modifications. Investigators should review the HRPO approval memorandum for each project and seek guidance at the HRPO website at https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo.
 - Research Involving Animals: For DOD awards that include funding to support animal studies, staff from the ACURO will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.
 - Inclusion Enrollment Report (IER): This is used to report the sex/gender, race, and ethnicity of study participants that will be enrolled in the clinical research (both planned and actual). The suggested IER format is a one-page fillable PDF form that may be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm> and completed for submission with the application.

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

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/application if necessary for evaluation.

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

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

C. Marking of Proprietary Information

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

D. Award Notices

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

1. **A procurement contract** is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the U.S. government (31 USC 6303). The award type, along with the start date, will be determined during the negotiation process.
2. **An assistance agreement (grant or cooperative agreement)** is appropriate when the federal government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.
3. **An Other Transaction Agreement (OTA)** is appropriate to carry out certain prototypes, research, and production projects. Other Transaction (OT) authorities were created to provide the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments.
4. After email notification that proposal/application review results can be found on eBRAP, and if the proposal/application is selected for funding, a representative from the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI’s organization.

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

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/application. Inquiries in response to funding recommendations should be

submitted to the USAMRAA Contracting or Grants Officer through the eBRAP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. The determination of an error in the review process is not a guarantee of funding. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the eBRAP Help Desk at help@eBRAP.org.

F. Information Service

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

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 (<https://www.justice.gov/oip>).

When an FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRDC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRDC’s intent to release and will be provided a reasonable opportunity to assert available action.

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.

The following statements must be included in all information releases:

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

“This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency J9, Research and Development Directorate, through the (*insert program name*) under Award No. (W81XWH-18-1-XXXX). Opinions, interpretations,

conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”

- (2) “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents, and information specified on the ACURO website (https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro).
- (3) “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<https://www.nih.gov>)
- (4) “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” ([Biosafety in Microbiological and Biomedical Laboratories—6th Edition \(cdc.gov\)](https://www.cdc.gov/biosafety/publications/m302/))

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 U.S. 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/Application Information

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

K. Sharing of Data and Research Resources

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

- **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large research data collections that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)
- **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens. (Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique.)
- **Research Resources** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools, methods, laboratory equipment and machines. (Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf.)

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

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

- **Traumatic Brain Injury (TBI):** If the project includes TBI research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) Informatics System (<https://fitbir.nih.gov>).
- **Clinical Trials:** If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database ClinicalTrials.gov (<https://www.clinicaltrials.gov/>).
- **Systems Biology (SB):** If the project includes 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/>).

Proposal/application information may be shared with other federal funding agencies (e.g., NIH, National Science Foundation, VA) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the web and to other

organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with federal funds. Updates on awards, including awardee information and published results are shared on DTIC.

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

L. Transfer of Award

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

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

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

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

M. Change of Principal Investigator

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

N. Property/Equipment

Contracts: Reference FAR Part 45 and DFARS Part 245.

Assistance Agreements: Unless otherwise specified in the award, the title to equipment or other tangible property acquired with government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research.

Normally, the title will vest in the awardee if vesting will facilitate scientific research performed by the organization for the government. Title to equipment or other tangible property acquired by for-profit organizations will conditionally vest in the organization subject to the requirements of the Department of Defense Grant and Agreement Regulations (DoDGARs), Part 34.21.

However, if the award is subsequently transferred to a new organization, DOD reserves the right to require the transfer of equipment acquired with the award funds to the federal government or to an eligible third party.

O. Title to Inventions and Patents

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

Contracts: FAR part 27 and DFARS Part 227

Assistance Agreements: DoDGARs 34.25 and 2 CFR 200.315-316

APPENDIX 3 QUALIFICATION AND RESTRICTIONS INFORMATION

A. Contractor/Recipient Qualification

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

The USAMRDC utilizes the Exclusions within the Performance Information functional area of System for Award Management (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 USAMRDC also reviews and considers information about the applicant in the Office of Management and Budget (OMB)-designated integrity and performance system, currently the Federal Awardee Performance and Integrity Information System (FAPIIS), prior to making an award, as described in the BAA, Section II.E.4.

B. Eligibility Information

Effective January 1, 2016, prior to making an award where the federal share is expected to exceed the simplified acquisition threshold (currently \$250,000) over the period of performance, the federal awarding agency is required to review information regarding the recipient that is available through FAPIIS. The recipient may submit comments to FAPIIS about any information that the federal awarding agency reported to FAPIIS, for consideration by the federal awarding agency in making future federal awards to the recipient.

In accordance with OMB's final guidance implementing the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (hereafter referred to as "Section 872"), as that statute applies to grants, effective January 1, 2016, recipients that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000, or for existing awards that are terminated on or after January 2, 2016, due to material failure to comply with the federal awards terms and conditions, are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award.

Recipients are required to disclose semiannually the information about the criminal, civil, and administrative proceedings that Section 872(c) describes. Reference Federal Register Notice, Vol. 80, No. 140, Wednesday, July 22, 2015.

General eligibility for investigators, organizations, and agencies:

- **Eligible Investigators:** Includes all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization. ***Note: Awards are made to organizations only, not individuals.*** Investigators must meet the specific BAA requirements.
- **Eligible Organizations:** Include national and international organizations. Eligible organizations include for-profit, non-profit, public, and private organizations, such as universities and colleges (including Historically Black Colleges and Universities, and Minority Institutions), hospitals, laboratories, and companies.
- **Government Agencies within the United States:** Local, state, and federal government agencies are eligible to the extent that proposals/applications do not overlap with their fully funded intramural programs. Such agencies are required to explain how their proposals/applications do not overlap with their intramural programs.

C. J-1 Visa Waiver

Each organization, including organizations located outside of the United States, are responsible for ensuring that the personnel associated with any proposal/application recommended for funding are able to complete the work without intercession by the 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 (<https://www.state.gov/state-sponsors-of-terrorism/>). Additional information on J-1 Visa Waivers can be located at the following Department of State website: travel.state.gov/visa/temp.

D. Conflict of Interest

1. Contract Awards

Organizational and Consultant Conflicts of Interest (COIs): 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/application, along with a plan to resolve them. An award may not be made if it is determined by the Contracting Officer that a COI cannot be avoided or managed.

2. Assistance Agreement Awards

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

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

3. Post-Employment Restrictions

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

APPENDIX 4 FORMATTING GUIDELINES

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

- **Document Format:** Each attachment to the full proposal/application forms must be uploaded as an individual file in the format specified in the BAA. All contributors to the proposal/application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing proposal/application components. The use of different software versions will result in corruption of the submitted file.
- **Font Size:** 12 point, not condensed.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-proposal/pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the proposal/application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the proposal/application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the BAA (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.

- **Recommended Attachment Size:** Individual attachments should be no larger than 20 MB. If the file size for the entire Grants.gov submission package will or may exceed 200 MB, applicants should contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that the file will be accepted or for other guidance.

APPENDIX 5 NATIONAL POLICY REQUIREMENTS

The National Policy Requirements are available in full text at <https://www.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 Research & Related Application for Federal Assistance Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

- (1) No federally appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any federal contract, the making of any federal grant, and the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than federally appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit SFLLL (Disclosure of Lobbying Activities), in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 USC 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

B. Representations

Extramural applicants are required to complete the representations below and submit with each proposal/application only if the organization is a Corporation and the response to item (2) or (3) is in

the affirmative.. The form for completion and submission is posted in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload the form into Grants.gov under Attachments.

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

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

- (1) Is _____ Is not _____ a Corporation (“Corporation” means any entity, including any institution of higher education, other 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 Research & Related Application for Federal Assistance Form, represents:

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

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

National Policy Requirements

The recipient must comply with the following requirements, as applicable. The 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
- FY21 National Defense Authorization Act (NDAA) Section 223(a), (a1) U.S. Code Title 18 Section 1001

APPENDIX 6 ACRONYM LIST

ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AL	Assistance Listing (formerly known as Catalog of Federal Domestic Assistance [CFDA]))
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
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
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DoDI	Department of Defense Instruction
DoDGARs	Department of Defense Grant and Agreement Regulations
DTIC	Defense Technical Information Center
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research
FMR	Financial Management Regulation
FOIA	Freedom of Information Act
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 Office

IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MPEG	Moving Picture Experts Group
NATO	North Atlantic Treaty Organization
NCAGE	NATO Commercial and Government Entity
NIH	National Institutes of Health
NTIS	National Technical Information Service
OMB	Office of Management and Budget
ONR	Office of Naval Research
ORCID	Open Researcher and Contributor Identification
ORP	Office of Research Protections
OT	Other Transaction
OTA	Other Transaction Agreement
PD	Project Director
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
R&R	Research and Related
RDT&E	Research, Development, Test and Evaluation
RM	Resource Management
SAM	System for Award Management
SB	Systems Biology
SCO	Senior Contracting Official
SF	Standard Form
SFLLL	Standard Form LLL (Disclosure of Lobbying Activities)
SOW	Statement of Work
TBI	Traumatic Brain Injury
TIFF	Tagged Image File Format
TIN	Tax Identification Number
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs
WAV	Waveform Audio