General Application Instructions for the Defense Health Agency Version CD26_01

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I. GENERAL INFORMATION

A. How to Use the General Application Instructions

The General Application Instructions (GAI) are designed to be read in conjunction with the program announcement for a funding opportunity offered by the Congressionally Directed Medical Research Programs (CDMRP). The program announcement provides basic information necessary to prepare an application (i.e., what to submit), whereas the GAI provides additional details and instruction for both application preparation and submission (i.e., how to submit). For accurate referencing, ensure that the version on the cover page of the GAI matches the version specified on the front page of the program announcement.

The following symbols are used throughout the GAI:

Marks particularly helpful or important information.

Refers the reader to the program announcement for specific instructions or additional information.

B. Current Funding Opportunities and Email Notifications

Funding opportunities currently issued by the CDMRP may be viewed at the Grants.gov Search Grants page; users should enter Assistance Listing (AL) Number 12.420 when searching for CDMRP funding opportunities. Applicants should subscribe on Grants.gov to receive official notifications of new funding opportunity postings and updates. Applicants are encouraged to sign up to receive notifications of changes to specific funding opportunities through either: (1) the Subscribe button on the Synopsis page for the specific program announcement; or (2) the Manage Subscriptions option on the Connect pull-down menu.

It is incumbent upon the applicant to check for published updates to the funding opportunity and the application package prior to submission; the applicant is responsible for using the latest version of the full application package. If the Grants.gov application package is updated or changed, then previous versions of the application package may not be accepted by Grants.gov.

Information about funding opportunities is available on the CDMRP Open Funding Opportunities page and on the electronic Biomedical Research Application Portal (eBRAP) Funding Opportunities and Forms page. Applicants can receive email notifications of funding opportunity releases by subscribing on eBRAP. Email notifications of funding opportunities from eBRAP are sent as a courtesy.

To facilitate that email correspondence is delivered correctly, and not treated as spam, Principal Investigators (PIs) and organizational representatives should keep email addresses up to date in both Grants.gov and eBRAP; and place the following domains into any available email "safelists": health.mil, eBRAP.org and Grants.gov. The same email addresses should be used when submitting both the pre-application and the full application.

C. Agency Contacts

eBRAP Help Desk: Questions related to program announcement content or submission requirements, as well as questions related to submission of pre-applications, or full applications

from intramural organizations, should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern Time (closed on most U.S. federal holidays). Response times may vary depending on the volume of inquiries. The eBRAP Help Desk will not provide Grants.gov submission assistance.

Phone: 301-682-5507

Email: Help@eBRAP.org

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

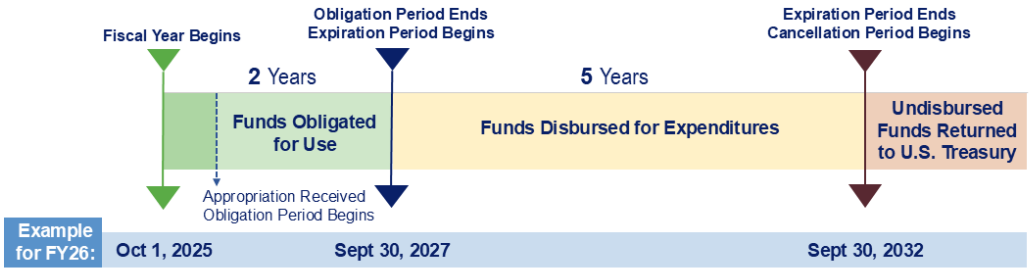
Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

D. Application and Award Information

Timelines: Awards made from CDMRP funding opportunities will be funded with Defense Health Program Research, Development, Test and Evaluation (RDT&E) appropriations. RDT&E funds must be obligated to a specific award or purpose within 24 months from the start of the fiscal year in which the funds were appropriated (e.g., fiscal year 2026 [FY26] funds must be obligated no later than September 30, 2027, Figure 1). In addition to obligation deadlines, RDT&E funds are available for use for a limited time period and close for disbursement five years after the obligation deadline. Closed (i.e., undisbursed) funds are returned to the U.S. Treasury at the end of the five-year disbursement period (e.g., FY26 funds close for disbursement to performers on September 30, 2032).

Figure 1. RDT&E Funds Obligation and Disbursement Timeline



Pre-Award Costs: An institution of higher education, hospital, other nonprofit or for-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs: (1) are necessary to conduct the project; and (2) would be allowable under the award, if awarded. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

Incurring pre-award costs in anticipation of an award imposes no obligation on the government to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The government expects the recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the organization's ability to accomplish the project objectives within the approved timeframe or in any way adversely affect the conduct of the project.

II. INTRODUCTION TO APPLICATION SUBMISSION

A. Applications Involving Intragovernmental or Intramural DOW Organizations

To provide information specific to intragovernmental and intramural DOW investigators contributing to the submission of an application, the CDMRP developed a Guide for Intragovernmental and Intramural DOD Applicants. Applicants are encouraged to reference this guide for additional information and considerations unique to intragovernmental and intramural organizations.

Funding to Intragovernmental and Intramural DOW Organizations: Intragovernmental and intramural DOW organizations must be prepared to accept the entirety of the requested budget for the proposed work in the fiscal year funds specified in the funding opportunity. Appropriations for a given CDMRP program or topic are not part of the requested DOW budget, and there is no guarantee of future funding. Intragovernmental and intramural DOW investigators are responsible for coordinating the use of funding agreements, contractual or otherwise, to support any extramural collaborators as appropriate. Intragovernmental and intramural DOW investigators and collaborators are reminded to coordinate the receipt and commitment of funds through their respective Resource Manager (RM), Task Area Manager, Comptroller or equivalent Business Official.

The Defense Health Agency Research and Development, Medical Research and Development Command (DHA R&D, MRDC) will "direct fund" Intragovernmental/Intramural DOW Organizations by utilizing Title 41 United States Code (USC) 6307, the Project Order Statute, or 31 USC 1535, the Economy Act Statute, as appropriate. Provided all criteria are met, the CDMRP will use the Project Order Statute as the preferred transactional authority to fund intramural DOW organizations. The DHA R&D, MRDC will fund by the authorized method through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD) or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals.

Funding of Extramural Organizations Collaborating with an Intragovernmental or Intramural DOW Organization: Direct transfer of funds from any extramural award recipient to an intragovernmental or intramural DOW organization is not allowed except under very limited

circumstances. As noted above, funding of intragovernmental or intramural DOW organizations, including research collaborators, will be managed through a direct funds transfer from the DHA R&D, MRDC.

Cooperative Research and Development Agreement (CRADA): If an extramural collaborator will be involved in the performance of the proposed research with an Intragovernmental or Intramural DOW organization, a CRADA or other instrument (as authorized by law or regulation) with the collaborator may be necessary before work between the organizations can begin. The CRADA (or other instrument) is not required at the time of application submission. A timeline for execution of the CRADA should be included within the project's Statement of Work (SOW).

B. Pre-Application and Full Application Submission Portal Systems

eBRAP is a secure web-based system that allows PIs and/or organizational representatives to receive communications from the CDMRP and to submit their pre-applications. Intramural DOW organizations may submit full applications through eBRAP.

Additionally, the eBRAP system allows a submitting organization's representatives and PIs to view and modify certain components of their full application submission package(s) during a specified verification period. eBRAP validates full application files against the specific program announcement requirements and notes discrepancies in an email to the PI as well as in the Full Application Files tab in eBRAP. During the verification period, it is the applicant's responsibility to review all application components for accuracy and to ensure proper ordering as specified in the program announcement. All verification periods are specified in the program announcement.

Grants.gov is an e-government system that provides a centralized location for grant seekers to find and apply for federal funding opportunities being openly competed. Full applications for CDMRP funding opportunities may only be submitted to Grants.gov after submission of a pre-application through eBRAP. ***Extramural organizations must submit full applications through Grants.gov.***

C. Application Submission Overview

Application submission is a two-step process. Successful completion of BOTH steps is required for all applications.

STEP 1. Pre-application submission: All pre-applications for both extramural and intramural DOW organizations ***must*** be submitted through eBRAP.

STEP 2. Full application submission: Full applications must be submitted through the online portals as described below.

> ***Grants.gov:*** Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Refer to Section IV, Full Application Submission Through Grants.gov, for application preparation and submission instructions.
>
> ***eBRAP:*** Only intramural DOW organizations may submit applications through eBRAP. Refer to Section V, Full Application Submission Through eBRAP, for application preparation and submission instructions. Full applications from extramural organizations, including non-DOW federal organizations, received through eBRAP will be withdrawn.

Regardless of submission portal used, all pre-application and application components must be submitted by the deadlines stipulated in the program announcement. Failure to meet any of the deadlines will result in application rejection.

The following information must be identical between the pre-application and the full application for eBRAP to process the submission: application title, PI information; Business Official(s) information, performing organization and contracting organization.

Additionally, the correct eBRAP log number associated with the application must be used throughout the entire submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP during the application verification period.

If the funding mechanism allows for Partnering PIs, the Defense Health Agency Contracting Activity (DHACA) requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The Partnering PI application is an abbreviated package that only includes components required to make a separate award. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***All associated applications (the Initiating PI's and Partnering PI's) must be submitted by the full application submission deadline.***

III. PRE-APPLICATION SUBMISSION

General information about eBRAP registration and pre-application submission is provided in this section. The eBRAP Applicant User Guide contains detailed instructions for these two processes.

A. eBRAP Registration

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

It is strongly recommended that PIs start the eBRAP registration process early to ensure sufficient time for completion prior to the submission deadline. There is no grace period.

PIs are required to utilize an Open Researcher and Contributor ID (ORCID) identifier and 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, the PI must invite an Authorized Organizational Representative (AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline in order for the pre-application to be submitted. ***However, the organization's eBRAP registration must be completed before the full application submission deadline to allow for processing, viewing and modifying select components of the full application package during the application verification period.***

Extramural Organizations: Applicants should ensure that the names and email addresses used during eBRAP registration are the same as the names and email addresses used on the Application for Federal Assistance Standard Form 424 (Research & Related), SF424 (R&R) Form, submitted through Grants.gov Workspace.

Intramural DOW Organizations: Applicants should ensure that the names and email addresses used during eBRAP registration are the same as the names and email addresses that will be provided when the full application package is submitted through eBRAP.

B. Content and Form of Pre-Application Submission – eBRAP

For specific instructions regarding content of the pre-application submission components, refer to Section 5.3.1, Pre-Application Submission, in the program announcement.

All pre-application components must be submitted through eBRAP by the deadline specified in the program announcement.

To start a new pre-application, select the New Pre-Application link associated with the relevant program and award mechanism, and follow the prompts in eBRAP. Select the appropriate submission type (i.e., extramural or intramural). Information used to identify the pre-application will be requested at this step, including application title, keywords and research characteristics.

The incorrect selection of submission type will delay processing.

If an error was made in selecting extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the eBRAP Help Desk to request a change in designation prior to full application submission.

Once a new pre-application is created, eBRAP will assign a unique eBRAP log number. The eBRAP log number remains with the application through the entire application and review process, and throughout the life of the award if the project is recommended for funding. Applicants should use this log number when referencing the application.

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

Summary Tab: This tab displays the information previously entered for the pre-application, such as application title, PI, Business Official, performing organization, contracting organization, etc. As the steps of the pre-application are completed, additional information will display on this tab.

Tab 1 – Application Information: This tab is prepopulated with information provided when creating a new pre-application. Prepopulated information can be changed in this tab, including the application submission type. Enter additional information as prompted.

Tab 2 – Application Contacts: Enter/update contact information for the PI and the Business Official responsible for sponsored program administration. For extramural applications, this will be the "Person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form. The Business Official must be either selected from the eBRAP list or invited to allow the pre-application to be submitted. If the Business Official cannot be found in eBRAP, an invitation must be sent to them to register in eBRAP. The invitation to register must be sent prior to the pre-application deadline, but the Business Official has until the full application deadline to complete the registration. This registration is required for the Business Official to view, modify and verify the application in eBRAP after submission.

Select the performing organization and the contracting organization. The organization(s) must be either selected from the options available in eBRAP or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

Tab 3 – Collaborators and Key Personnel: Enter the name, organization and role of all collaborators and key personnel associated with the application, including partnering PI(s), if applicable.

No member of the Programmatic Panel may be named as a Collaborator or Key Personnel for the proposed research project, nor assist in preparing or submitting any component of the pre-application or application. Refer to the specific program announcement for a link to the list of Programmatic Panel members.

Tab 4 – Conflicts of Interest: To avoid conflicts of interest during the screening and review processes, list all individuals, other than collaborators and key personnel, who may have a conflict of interest in the review of the application. Include individuals with whom the PI has a personal or professional relationship.

Tab 5 – Pre-Application Questions and/or Files: Upload individual PDF files and/or enter requested data in specified text boxes: refer to the program announcement for any detailed program specific instructions. Documents should conform to the formatting guidelines outlined in Appendix 2.

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

Following completion of pre-application submission, the status of the pre-application in eBRAP will change from DRAFT to SUBMITTED and a confirmation email will be sent to the PI and the named Business Official.

The pre-application is not submitted until Tab 6 is complete. Pre-applications not submitted remain in DRAFT status. An applicant with a pre-application in DRAFT status after the pre-application submission deadline is ineligible to submit a full application. There is no grace period.

IV. FULL APPLICATION SUBMISSION THROUGH GRANTS.GOV

A. Grants.gov Registration

To apply through Grants.gov, an organization, foreign or domestic, must first complete the Grants.gov registration process. ***Allow up to eight weeks for the completion of the Grants.gov registration process; this could take longer if the organization does not already have a unique entity identifier (UEI) from SAM.gov.*** Registering early is advised.

Foreign organizations doing business outside of the U.S. must also fulfill any/all supplementary requirements for doing business with the U.S. government. If business is conducted with the federal government on a continuing basis, it is likely that some of the required actions have already been completed. Detailed information, links, automated tools and checklists are available at the Grants.gov Quick Start Guide for Applicants page.

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

1. Obtain Unique Entity Identifier from System for Award Management

The applicant organization must be registered as an Entity in the System for Award Management (SAM.gov) and receive confirmation of an Active status before submitting an application through Grants.gov. ***All federal awards, including but not limited to grants, cooperative agreements and contracts, must use the UEI generated by the SAM.***

The SAM validates organization information and electronically shares the secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an electronic business (E-Biz) POC, and a government business POC during the SAM registration process. ***Entity registrations in SAM have an annual expiration. Verify the status of your organization's entity registration in the SAM well in advance of the application submission deadline.*** If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least five weeks to receive this information from the U.S. Internal Revenue Service. ***Once an EIN or TIN is obtained, allow three to four weeks to complete the entire SAM registration process.***

Additional information and step-by-step registration directions are detailed in the SAM User Guide and other U.S. General Services Administration (GSA) training materials at the SAM.gov Help page.

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. Obtain a 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 the SAM must be assigned a North Atlantic Treaty Organization CAGE code (NCAGE). An NCAGE code can be obtained by

contacting the National Codification Bureau of the country where the organization is located or by visiting CAGE. Validation of the CAGE code or NCAGE code in the SAM can take 10 to 15 business days to process after the EIN or TIN is validated.

3. Register an AOR

An AOR is the Business Official designated as a member of the Grants.gov Workspace grant team who is authorized to submit the completed Workspace full application package. At the time of application submission to Grants.gov, the AOR certifies that, to the best of their knowledge, all information provided in the application is current, accurate and complete. For applications submitted through Grants.gov, the name of the AOR submitting the application is inserted into the application's signature line, serving as the electronic signature.

An AOR must first register with the Grants.gov credential provider at Grants.gov to obtain a username and password. PIs do not register with Grants.gov. Once an AOR has completed the registration process, Grants.gov will notify the E-Biz POC of the registration; an individual may serve as both the E-Biz POC and the AOR. The E-Biz POC must then log in to Grants.gov and assign and authorize the appropriate roles, giving the AOR permission to complete and submit applications on behalf of the organization. After the E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

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

4. Create Grants.gov Workspace

Applicants must create a Grants.gov Workspace, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Once the Workspace has been created, participants (grant team members) can be added, and the required forms can be completed and reviewed before submitting. Specific information regarding the application process through Grants.gov Workspace is available on the Grants.gov How to Apply For Grants page.

Each application submission must include the completed application package of forms associated with the specific funding opportunity in Grants.gov.

Applicants who prepare the application outside Workspace must download the individual PDF forms from Grants.gov, complete and save the forms, and upload them to Workspace. Ensure a version of Adobe Acrobat Reader that is compatible with Grants.gov is used to download, complete and submit grant applications. If multiple users are completing Workspace PDF forms, it is recommended that the same version of Adobe Acrobat Reader software be used by each user to avoid version compatibility issues. It is the applicant's responsibility to verify their Adobe software's compatibility with Grants.gov.

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

B. Content and Form of Full Application Submission – Grants.gov

The following information must be identical between the pre-application and the full application for eBRAP to process the submission: application title, PI information; Business Official(s) information, performing organization and contracting organization.

Additionally, the correct eBRAP log number associated with the application must be used throughout the entire submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify and verify the application in eBRAP during the application verification period.

(a) SF424 (R&R) – Application for Federal Assistance Form

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

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

- **Block 2 – Date Submitted.** Enter the date the application is submitted.

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

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

- **Block 4a – Federal Identifier.** Enter the eBRAP log number assigned during pre-application submission.

Entering the eBRAP log number in Block 4a is a critical step to link the pre-application to the full application.

- **Block 4b – Agency Routing Identifier.** Not applicable.

- **Block 4c – Previous Grants.gov Tracking ID.** For changed/corrected applications, enter the Grants.gov Tracking Number for the original application.

- **Block 5 – Applicant Information.** Enter the information for the applicant organization. The "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 U.S. 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. Indicate whether the application is, or will be, submitted to other agencies.

- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** Find your congressional district at the U.S. Census My Congressional District page. If the applicant organization is outside the United States, enter 00000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the application. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget Form.
- **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" checkbox to provide the required certifications and assurances**.** By checking "I agree" on the SF424 (R&R) Form in block 17, you agree to abide by the following:
    - By signing this application, I certify: (1) to the statements contained in the list of certifications; and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious or fraudulent statements or claims may subject me to criminal, civil or administrative penalties. Refer to 18 USC 1001, the Statements or Entries Generally section of the Crimes and Criminal Procedure.
    - 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 terms of the award; (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act. Refer to 42 USC 6605(a), the Disclosure Requirement subsection of Disclosure of Funding Sources in Applications for Federal Research and Development Awards.
    - Compliance with the National Policy Requirements noted in Appendix 8.

- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL (SFLLL) to disclose lobbying activities pursuant to 31 USC 1352, Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions.

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

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

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

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

(b) Attachments Form

Grants.gov does not validate for the presence of attachments on the Attachments Form.

Each attachment in the Attachments Form must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2. Use of PDF portfolios is discouraged. For all attachments, ensure that the file names are consistent with the guidance in the program announcement and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, period, parenthesis, curly braces, square brackets, ampersand, tilde, exclamation point, comma, semi colon, apostrophe, at sign, number sign, dollar sign, percent sign, plus sign and equal sign. Grants.gov suggests limiting the file size of the entire grant application package including all the attachments to 200MB.

Do not password protect any files of the application package.

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

For specific instructions regarding application attachments, attachment numbers, content and page limits, refer to Section 4.3, Full Application Components, in the program announcement. Attach each as a separate PDF file, named as specified in the announcement.

The following must be included as attachments unless otherwise stated in the funding opportunity:

- **Project Narrative: Attach as "ProjectNarrative.pdf".** The Project Narrative is the main body of the application. The page limit applies to text and non-text elements (e.g.,

figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

- **Supporting Documentation: Combine and attach as a single PDF file named "Support.pdf".** Begin each document on a new page. 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. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed, or the application may be administratively withdrawn. ***Letters of support not requested in the program announcement, such as those from members of Congress, will be removed from the application package.***

A complete list and descriptions of required Supporting Documentation is included in the program announcement.

- **Technical Abstract: Attach as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of funded research projects are posted publicly. ***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.

- **Lay Abstract: Attach as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. Abstracts of all funded research projects will be posted publicly. ***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. ***Do not duplicate the Technical Abstract.***

- **Statement of Work: Attach as "SOW.pdf".** The SOW is an outline of the proposed research project that includes the specific aims, proposed tasks and project milestones that will be accomplished during the award period of performance. All study site locations should be listed, including the country(s) where DOW-funded research will be performed. The SOW should contain sufficient detail to be informative as a stand-alone document, and there is no limit to the number of specific aims, tasks or subtasks that are described within the SOW page limit. Applicants are strongly encouraged to use the suggested SOW format available on eBRAP and to follow the detailed guidance provided within the Examples to prepare their SOWs.

- **Suggested Intragovernmental/Intramural Budget Form, *if applicable*: Attach as "IGBudget.pdf".** If an intramural DOW organization will collaborate in the performance of the project, complete a separate Suggested Intragovernmental/Intramural Budget Form for each intramural DOW organization involved in the project and upload as a single document. For additional support, review the detailed instructions for completing the Suggested Intragovernmental/Intramural Budget Form.

C. Additional Application Materials

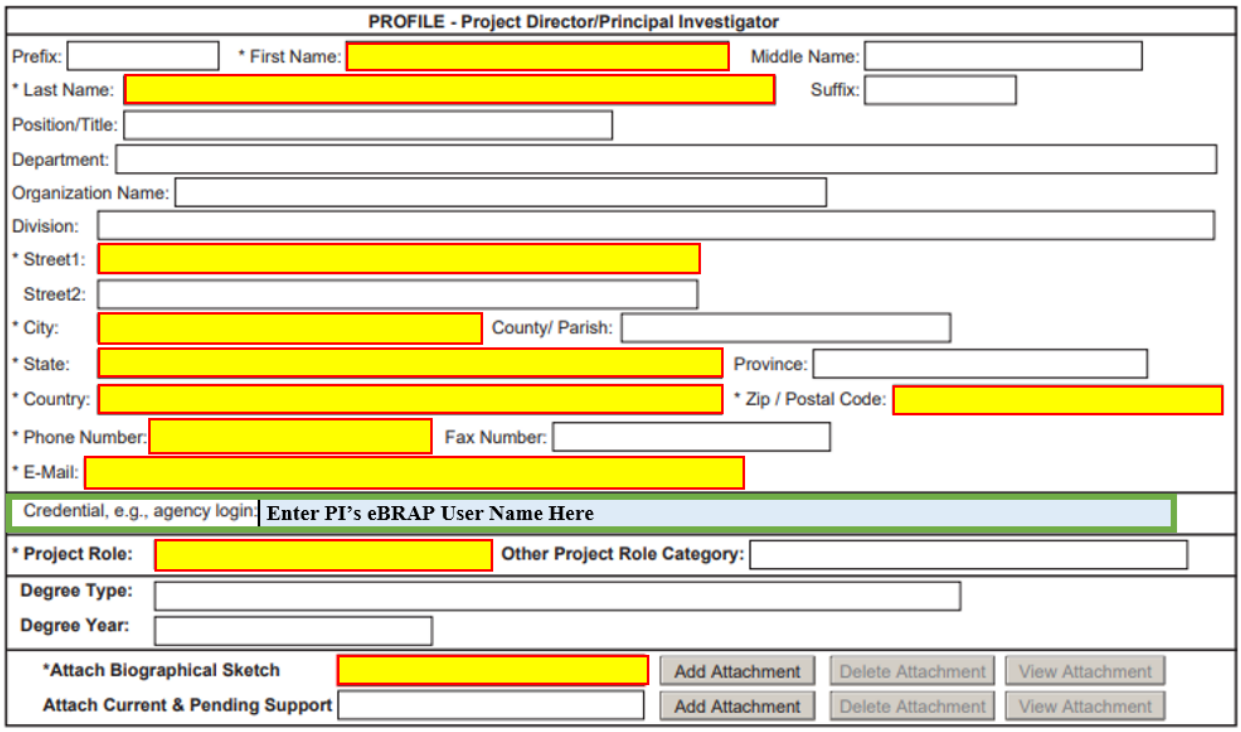
The following are additional application materials for application submission. Follow the instructions provided to prepare each: Research & Related Senior/Key Person Profiles, Biographical Sketches, Current/Pending Support documentation, Research & Related Budget forms, Project/Performance Site Location(s) forms, and Research & Related Subaward Budget Attachment(s) forms.

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

Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project, including the provision of degree information. All fields marked with an asterisk are required. For the application PI, in the "PROFILE – Project Director/Principal Investigator" section, enter the PI's User Name provided by eBRAP into the data field labeled "Credential, e.g., agency login" (Green Box, Figure 2). Additional Senior/Key persons can be added by selecting the Next Person button.

A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

Figure 2. PI's eBRAP User Name



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

  The CDMRP staff and reviewers utilize the biographical sketch to ensure that research teams are equipped with the expertise necessary to carry out the proposed research.

Applicants may use the instructions provided within the Biographical Sketch Common Form to construct a biographical sketch, or may use a PDF form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

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

  Applicants may use the instructions provided within the Current and Pending (Other) Support Common Form to construct current and pending support documentation, or may use a PDF form created in SciENcv for NIH or NSF.

ii. Research & Related Budget

The Budget and Budget Justification is used by the CDMRP staff and reviewers to determine whether proposed costs are allowable, allocable and reasonable for the proposed research.

An estimate of the total cost for the proposed research, with a breakdown of all cost categories for each year of the project, must be submitted using the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs and period of performance, refer to the program announcement. ***A budget justification for the entire period of performance must be uploaded to Section L in the Budget Period 1 portion of the Research & Related Budget Form.*** The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable and reasonable for the proposed research. At the time of application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate and complete. The government reserves the right to request a revised budget and budget justification and/or additional information.

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

Budget Regulations and Restrictions:

- **Administrative and Cost Principles:** Recipients are required to comply with the following, as applicable:

  - Code of Federal Regulations, Title 2, Part 200, or 2 CFR 200, Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, as implemented by Chapter XI of Title 2 CFR.

  - Provisions of Chapter I, Subchapter C of 32 CFR, DOD Grant and Agreement Regulations, specifically: (1) 32 CFR 26, Governmentwide Requirements for Drug-Free Workplace (Financial Assistance); (2) 32 CFR 28, New Restrictions on Lobbying; and (3) 32 CFR 34.16, Audits; and also 2 CFR, Chapter XI, Parts 1100-1199, Federal Agency Regulations or Grants and Agreements for the Department of Defense.

- Federal Acquisition Regulation (FAR) Part 31, Contract Cost Principles and Procedures.

It is prohibited to charge a fee or profit to an assistance agreement, either by the recipient/awardee or subrecipient/subawardee.

- **Cost of Preparing Applications:** The cost of preparing applications in response to a program announcement is not considered an allowable direct charge to any resultant award.

- **Currency:** All costs must be entered in U.S. dollars.

Budget Instructions: Complete Sections A through L of the Research & Related Budget Form following the instructions below. Begin by entering the organizational UEI, Budget Type, Name of Organization and anticipated start and end dates. Funds requested should be specific to the proposed research project and should be consistent with the work outlined in the Project Narrative and SOW.

Ensure that the UEI is entered accurately or Grants.gov will reject the application.

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 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).

- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. 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 application is recommended for funding, the organization may be requested to provide documentation to support the fringe benefits

(e.g., the current U.S. 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.

Section B: Other Personnel

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

- **Project Role:** Identify each project role category.

- **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 application is recommended for funding, the organization may be requested 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 one year and a per-unit acquisition cost that equals or exceeds the lesser of: (1) $5,000; or (2) the recipient's or the subrecipient's capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research.

Section D: Travel. Enter the total funds requested for travel. Applicants are responsible for budgeting all costs associated with travel, including airfare, hotel, etc. Refer to the specific program announcement for instructions regarding required travel and/or travel limitations.

Funds to an extramural organization may not be used to cover travel costs for DOW military and civilian employees. All approved travel costs for DOW military and civilian employees will be paid by the government through a direct fund transfer. Proposed travel costs for DOW military and civilian employees should be included on the Suggested Intragovernmental/Intramural Budget Form.

Section E: Participant/Trainee Support Costs. Enter the funds requested for tuition/fees/health insurance, stipends, travel, subsistence and other costs. Include the number of participants/trainees that the requested costs will support.

Section F: Other Direct Costs

1. **Materials and Supplies:** Materials and supplies are all tangible property, including a computing device, acquired under an award that does not meet the definition of equipment.

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

3. **Consultant Services:** Include the total funds requested for consulting services.

4. **Automated Data Processing (ADP)/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical and education information.

5. **Subaward/Consortium/Contractual Costs:** Include the total funds requested for: (1) all subaward/consortium organization(s) proposed for the research project (direct and indirect costs); and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the Research & Related Subaward Budget Attachment(s) Form, or in the Suggested Intragovernmental/Intramural Budget Form if the subaward is to an intramural organization. For further instructions, refer to Research & Related Subaward Budget Attachment(s) Form.

All direct and indirect costs of any subaward, including intragovernmental/intramural collaborators, must be included in the direct costs of the primary award.

6. **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees.

7. **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. ***Costs for the construction of facilities are not allowable.***

8. **Other Expenses:** Use lines 8-17 to itemize other anticipated direct costs as needed (e.g., communication costs, organizationally provided core services). If the proposed research project includes research-related human subjects costs, the requested funds are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs. State the total direct costs (i.e., summation of Sections A-F) for the budget period.

The primary award (including the direct and indirect costs of any subawardees, if applicable) should not exceed the cost cap stated in the program announcement.

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. ***No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate.***

In accordance with 2 CFR 200.414(f), De Minimis Rate, a nonfederal entity that does not have a current negotiated (including provisional) rate may elect to charge a de minimis rate of 15% 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 nonfederal entity chooses to negotiate for a rate.

Organizations can also visit the websites for the DHHS, the Office of Naval Research and the Defense Contract Audit Agency for additional information on indirect rates.

Section I: Total Direct and Indirect Costs. State the total costs (i.e., summation of Sections G and H) for the budget period.

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

Section K: Total Costs and Fee. As it is prohibited to charge a fee or profit to an assistance agreement, the value in Section K should equal the value in Section I.

Section L: Budget Justification. Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to Section L in the Budget Period 1 portion of the Research & Related Budget Form. It is recommended that the headings of the cost categories in the budget justification match the cost categories in the Research & Related Budget Form. Itemize direct costs for all years of the award. Organizations must provide sufficient detail and justification so the government can determine that the proposed costs are allowable, allocable and reasonable for the proposed research. Applicants performing research outside of the United States should also 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 applicants performing research outside of the United States will be determined at the time of application submission.

> **Personnel:** Identify the role of each Senior/Key person listed and describe their specific functions for the proposed research. Identify and explain any proposed adjustments to labor rates or salaries.
>
> **Equipment:** If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (1) special test equipment to be fabricated for specific research purposes and its cost; (2) standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately; and (3) existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment

those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for federal income tax purposes.

Travel: If travel costs are requested to attend scientific/technical meetings, include the meeting name, purpose, location and date, if known. International travel may be requested but must be justified with additional documentation and is subject to approval by the Grants Officer. The justification should clearly confirm that the requested travel costs meet any travel requirements and/or restrictions stated in the program announcement.

Materials and Supplies: Include a general description of expendable material and supplies for each year. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost and description. If a computer/software purchase is requested, include a detailed explanation for why purchase of computer/software is required to complete the proposed research project. Include a statement verifying that the requested computer/software is not currently available for use.

Consultant Services: Independent of whether funds are requested for any proposed consultant services, include the name(s) and organizational affiliation(s) of all consultants; provide the daily consultant fee and any travel expenses; and describe nature of the consulting effort, including why consultants are required for the proposed research.

Equipment or Facility Rental/User Fees: List the proposed equipment or facility rental/user fees, including data processing fees. Include information regarding estimated hours/units required for the proposed research and the provider's service rates.

Alterations and Renovations: Provide a description of the existing facility and detailed description of the requested changes. Include a justification outlining how changes directly support the proposed research. ***Costs for the construction of facilities are not allowable*.**

Other Direct Costs: Describe and justify any other requested direct cost categories.

Indirect Costs: 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 whether the rate(s) is an on-site or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Federal Financial Plan: The CDMRP's funding for each program is signed into law on a yearly basis and is obligated up front for each award as there is no guarantee of future program appropriations. Funds are available for obligation for two years from the beginning of the fiscal year of appropriation. For applications involving an intragovernmental or intramural DOW organization, include a federal financial plan in the budget justification. The plan must address how any funds transferred to the intragovernmental or intramural DOW organization 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, if applicable. The CDMRP encourages intramural DOW applicants to plan for the transfer of funding via Project Orders, where applicable. ***Unless otherwise stated in the funding opportunity, the CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.***

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

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

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

iii. 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.

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

Extramural Subaward(s): Complete a separate Research & Related Budget Form, including a budget justification, for each subaward (subgrant or contract) in accordance with the instructions described above. Title each individual subaward document "Research & Related Budget" with the name of the subaward recipient organization and attach to the Research & Related Subaward Budget Attachment(s) Form.

Intramural DOW Subaward(s): Complete a separate Suggested Intragovernmental/Intramural Budget Form, including a budget justification, for each intramural subaward, using the instructions in Section VI, Full Application Submission Through eBRAP, and upload as a single document titled "IGBudget.pdf**"** to the Grants.gov Attachments Form.

All direct and indirect costs of any subaward must be included in the direct costs of the primary award. The primary award cannot exceed the cost cap stated in the program announcement.

D. Submission to Grants.gov

Grants.gov strongly recommends submitting the application package at least 24-48 hours prior to the close date to provide time to prevent technical issues from disrupting application submission.

All applications must be received by the deadline specified in the program announcement. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the application's timely submission. The submission of a Workspace package can be tracked from the Workspace or by visiting Grants.gov and entering the Tracking Number.

E. Applicant Verification of Grants.gov Submission in eBRAP

Once the full application is submitted to Grants.gov, it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the Full Application Files tab. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement.

The Project Narrative and the Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted to Grants.gov prior to the full application submission deadline.

Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

The full application submission deadline and the end of the application verification period are stated in Section 1, Basic Information About the Funding Opportunity, of the specific program announcement.

V. FULL APPLICATION SUBMISSION THROUGH eBRAP

Only intramural DOW organizations may submit applications through eBRAP.

A. Content and Form of Full Application Submission – eBRAP

(a) eBRAP Full Application Package Components

The eBRAP full application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to your My Applications page and click Start Full Application** for the log number under which the pre-application was submitted.

- **Tab 1 – Summary:** Provides a summary of the application information and copies of standard application forms.
- **Tab 2 – Contacts:** This tab will be populated by eBRAP. Add the name of the AOR.
- **Tab 3 – Full Application Files:** Upload each application component in eBRAP as individual PDF files.
- **Tab 4 – Application and Budget Data:** Review and edit the Proposed Project Start Date, Proposed End Date and budget data that is pre-populated from the Budget Form.
- **Tab 5 – Submit/Request Approval Full Application:** Once all components have been uploaded, and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the Submit Full Application button. eBRAP will validate files against the program announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the Confirm Submission button to complete the application submission. eBRAP will notify the RM/Comptroller/Task Area Manager or equivalent Business Official by email to log in to eBRAP to review and approve the full application package prior to the approval deadline.

(b) Attachments

Application components for intramural submissions are identical to those mentioned above for extramural submission, unless otherwise stated below.

Upload attachments to Tab 3 – Full Application Files. Each attachment must be uploaded as an individual PDF file, unless otherwise stated. Refer to Appendix 2 for detailed formatting guidelines. Use of PDF portfolios is discouraged. For all attachments, ensure that the file names are consistent with the guidance in the program announcement and below.

Do not password protect any files of the application package.

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

For specific instructions regarding application attachments, attachment numbers, content and page limits, refer to Section 4.3, Full Application Components, in the program announcement. Attach each as a separate PDF file, named as specified in the announcement.

The following must be included as attachments unless otherwise stated in the funding opportunity:

- **Project Narrative: Attach as "ProjectNarrative.pdf".** The Project Narrative is the main body of the application. The page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

- **Supporting Documentation: Combine and attach as a single PDF file named "Support.pdf".** Begin each document on a new page. 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. Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed, or the application may be administratively withdrawn. ***Letters of support not requested in the program announcement, such as those from members of Congress, will be removed from the application package.***

A complete list and descriptions of required Supporting Documentation is included in the program announcement.

- **Technical Abstract: Attach as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of funded research projects are posted publicly. ***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.

- **Lay Abstract: Attach as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. Abstracts of funded research projects are posted publicly. ***Do not include proprietary or confidential information. Do not duplicate the Technical Abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- **Statement of Work: Attach as "SOW.pdf".** The SOW is an outline of the proposed research project that includes the specific aims, proposed tasks and project milestones that will be accomplished during the award period of performance. All study site locations should be listed, including the country(s) where DOW-funded research will be performed. The SOW should contain sufficient detail to be informative as a stand-alone document and there is no limit to the number of specific aims, tasks or subtasks that are described within the SOW page limit. Applicants are strongly encouraged to use the suggested SOW format available on eBRAP and to follow the detailed guidance provided within the Examples to prepare their SOWs.

B. Additional Application Materials

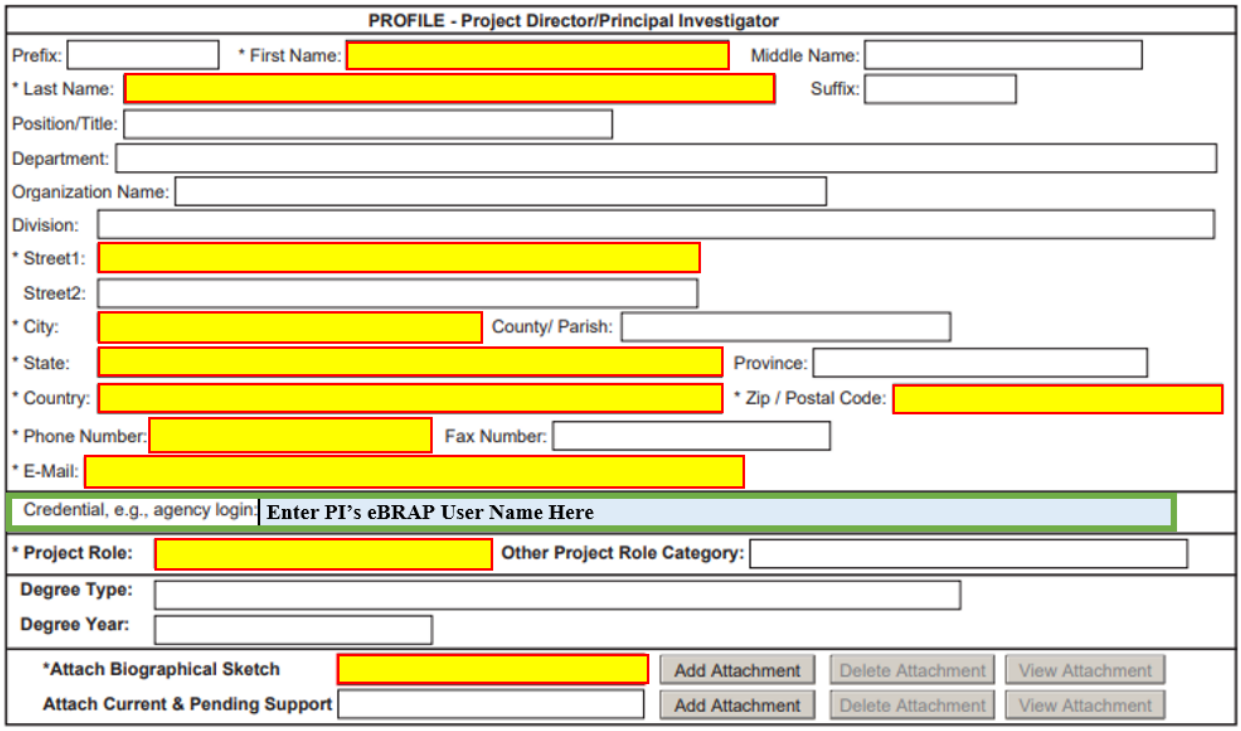
The following are additional application materials for application submission. Follow the instructions provided to prepare each: Research & Related Senior/Key Person Profiles,

Biographical Sketches, Current/Pending Support Documentation, Budget forms, and Project/Performance Site Location(s) forms.

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

Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project, including the provision of degree information. All fields marked with an asterisk are required. For the application PI, in the "PROFILE – Project Director/Principal Investigator" section, enter the PI's User Name provided by eBRAP into the data field labeled "Credential, e.g., agency login" (Green Box, Figure 3). Additional Senior/Key persons can be added by selecting the Next Person button.

Figure 3. PI's eBRAP User Name



A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the Research & Related Senior/Key Person Profile (Expanded) Form or uploaded as individual files within Tab 3 – Full Application Files.

Upload the Research & Related Senior/Key Person Profile (Expanded) as "KeyPersonnel_LastName.pdf" to Tab 3 – Full Application Files.

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

  The CDMRP staff and reviewers utilize the biographical sketch to ensure that research teams are equipped with the expertise necessary to carry out the proposed research.

Applicants may use the instructions provided within the Biographical Sketch Common Form to construct a biographical sketch, or may use a PDF form created in SciENcv for the NIH or NSF.

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

  Applicants may use the instructions provided within the Current and Pending (Other) Support Information Common Form to construct current and pending support documentation, or may use a PDF form created in SciENcv for NIH or NSF.

ii. Budget Form

The Budget and Budget Justification is used by the CDMRP staff and reviewers to determine whether proposed costs are allowable, allocable and reasonable for the proposed research.

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year of the project, must be submitted. Complete a separate Suggested Intragovernmental/Intramural Budget Form that covers all years of the period of performance for each research site involved in the project (including subaward sites) and upload to Tab 3 – Full Application Files as a single document titled "IGBudget.pdf". The Suggested Intragovernmental/Intramural Budget Form is available for download on eBRAP. For limits on funding amounts, types of costs and period of performance, refer to the program announcement. ***A budget justification for the entire period of performance that includes a Federal Financial Plan must be appended to the Suggested Intragovernmental/Intramural Budget Form.*** The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable and reasonable for the proposed research. The government reserves the right to request a revised budget and budget justification and/or additional information.

If the budget fails eBRAP validation, the PI will receive an error message and will be required to correct the budget within the existing application prior to the full application submission deadline. Any additional modifications to the budget must also be completed prior to the full application submission deadline.

Budget Regulations and Restrictions:

- **Administrative and Cost Principles:** Recipients will be required to comply with the following, as applicable:

  - 2 CFR 200, Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, as implemented by Chapter XI of Title 2 CFR.

  - Provisions of Chapter I, Subchapter C of 32 CFR, DOD Grant and Agreement Regulations, specifically: (1) 32 CFR 26, Governmentwide Requirements for Drug-Free Workplace (Financial Assistance); (2) 32 CFR 28, New Restrictions on Lobbying; and (3) 32 CFR 34.16, Audits; and also 2 CFR, Chapter XI, Parts 1100-1199, Federal Agency Regulations or Grants and Agreements for the Department of Defense.

  - FAR Part 31, Contract Cost Principles and Procedures.

- **Cost of Preparing Applications:** The cost of preparing applications in response to a program announcement is not considered an allowable direct charge to any resultant award.

- **Currency:** All costs must be entered in U.S. dollars.

Intragovernmental/Intramural Budget Form Instructions:

Begin by entering the organization name, PI name and eBRAP Log number in the fields at the top.

- **Name:** Beginning with the PI, list all key personnel who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable) and support staff who will contribute significantly to the proposed research.

DOW Civilian and Military Personnel: Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any federal employee. Generally, RDT&E funds may only be requested to support civilian salaries for those individuals who are in reimbursable positions. These circumstances will be discussed during award negotiations and will require substantial justification in the Budget Justification section.

- **Role/Key Personnel:** Identify the role of each participant listed. Describe their specific functions in the proposed research in the budget justification.

- **Title/Position/Rank:** Identify the title, position or rank for each individual.

- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual requesting salary reimbursement listed for the project. If no reimbursement is requested, leave the Annual Base Salary section blank.

- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.

- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.

- **Totals:** Calculated automatically from the salaries and fringe benefits data provided. Ensure the auto-calculated totals are correct.

- **Consultant Costs:** List the total costs for any consultant fees/services.

- **Equipment:** Provide the cost of proposed equipment. Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost that equals or exceeds the lesser of: (1) $5,000; or (2) the recipient's or the subrecipient's capitalization threshold for financial statement

purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research.

- **Materials and Supplies:** Materials and supplies are all tangible property, including a computing device, acquired under an award that does not meet the definition of equipment.

- **Military and Federal Civilian Travel Costs:** Applicants are responsible for budgeting all costs associated with travel, including airfare, hotel, etc. Anticipated travel costs should be built into the budget at current or projected DOW per diem rates. ***Military and federal civilian travel costs cannot be subjected to fees/indirect costs unless funded via a project order.***

- **Contractor Travel Costs:** For contractor personnel, indicate all travel costs associated with travel, including airfare, hotel, etc. Anticipated travel costs should be built into the budget at current or projected DOW per diem rates.

- **Other Direct Costs:** Itemize other anticipated direct costs such as research-related human subjects cost, equipment rental (provide hours and rates), communication costs, etc. Estimate the costs of publishing and reporting research results, including direct charges for clerical services, illustrations, reprints and distribution. Organizationally provided core services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.

- **Sub-Award/Contract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. The nature of the partnership/collaboration should be described in the Sub-Award/Contract Budget Justification section.

All direct and indirect costs of any subaward/contract must be included in the direct costs of the primary award.

- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period and for the entire proposed period of support.

The primary award (including the direct and indirect costs of any subawardees/subcontractors, if applicable) should not exceed the cost cap stated in the program announcement.

- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the Justification section. The government reserves the right to disallow any indirect costs not sufficiently justified. No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate.

- **Total Direct and Indirect Costs:** This section is calculated automatically from the data provided.

- **Required Information (last page of the form):**

- Indicate the name and contact information for the RM, Business Official and any parties who should be included on budgetary matters.

- Indicate the last date the institution can accept current fiscal year funds.

- The authorized organization representative must: (1) attest that the organization has a system in place to accept funds; (2) acknowledge that receipt of funds may occur within the last six months of the current fiscal year; and (3) sign the document.

Budget Justification Instructions:

Provide a clear budget justification for the entire period of performance for each item in the budget. ***Append the Budget Justification to the Suggested Intragovernmental/Intramural Budget Form and upload as a single document.*** It is recommended that the headings of the cost categories in the budget justification match the cost categories in the Suggested Intragovernmental/Intramural Budget Form. Itemize direct costs for all years of the award. Organizations must provide sufficient detail and justification so the government can determine that the proposed costs are allowable, allocable and reasonable for the proposed research. Applicants performing research outside of the United States should also 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 applicants performing research outside of the United States will be determined at the time of application submission.

Personnel: Identify the role of each Senior/Key person listed and describe their specific functions in the budget justification. Identify and explain any proposed adjustments to labor rates or salaries.

Equipment: If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (1) special test equipment to be fabricated for specific research purposes and its cost; (2) standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately; and (3) existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for federal income tax purposes.

Travel: If travel costs are requested to attend scientific/technical meetings, include the meeting name, purpose, location and date, if known. Support for international travel may be requested but must be justified with additional documentation and is subject to approval by the Program Office. The justification should clearly confirm that the requested travel costs meet any travel requirements and/or restrictions stated in the program announcement.

Materials and Supplies: Include a general description of expendable material and supplies for each year. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost and description. If a computer/software purchase is requested, include a detailed explanation for why purchase of computer/software is

required to complete the proposed research project. Include a statement verifying that the requested computer/software is not currently available for use.

Consultant Services: Independent of whether funds are requested for any proposed consultant services, include the name(s) and organizational affiliation(s) of all consultants; provide the daily consultant fee and any travel expenses; and describe nature of the consulting effort, including why consultants are required for the proposed research.

Service Costs and User Fees: List proposed equipment or facility rental/user fees, including data processing fees. Include information regarding estimated hours/units required for the proposed research project and the provider's service rates.

Alterations and Renovations: Provide a description of the existing facility and detailed description of the requested changes. Include a justification outlining how changes directly support the proposed research. ***Costs for the construction of facilities are not allowable.***

Other Expenses: Describe and justify any other anticipated direct cost categories.

Indirect Costs: 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-site or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.

Federal Financial Plan: The CDMRP's funding is directed by Congress on a yearly basis for each program and is obligated up front for each award as there is no guarantee of future program appropriations. Funds are available for obligation for two years from the beginning of the fiscal year of appropriation. For applications involving an intragovernmental or intramural DOW organization, include a federal financial plan in the budget justification. The plan must address how any funds transferred to the intragovernmental or intramural DOW organization 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, if applicable. The CDMRP encourages intramural DOW applicants to plan for the transfer of funding via Project Orders, where applicable. ***Unless otherwise stated in the funding opportunity, the CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.***

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

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

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

iii. 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.

Upload the Project/Performance Site Location(s) Form as "Performance.pdf" to Tab 3 – Full Application Files.

C. Applicant Verification of Full Application Submission in eBRAP

Upon application submission, the organizational RM/Comptroller/Task Area Manager or equivalent Business Official will receive an email instructing them to log in to eBRAP to review and approve the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the Full Application Files tab. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. Verification of application content is strongly recommended but not required. Modifications to application components may only be made after the Business Official has set the status to "Return to PI" for the PI to make changes, or to "Draft" for the Business Official to make changes.

The Project Narrative and the Intragovernmental/Intramural Budget Form cannot be changed after the application submission deadline.

Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends. The RM/Comptroller/Task Area Manager or equivalent Business Official should log in to eBRAP to review and to approve the application package prior to the application verification deadline.

The full application submission deadline and the end of the application verification period are stated in Section 1, Basic Information About the Funding Opportunity, of the specific program announcement.

APPENDIX 1.
RECIPIENT QUALIFICATION AND RESTRICTION INFORMATION

A. Recipient Qualification

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. According to part 22.415 of the Department of Defense Grant and Agreement Regulations (DoDGARs), or 32 CFR 22.415, Standards, a potential qualified recipient must: (1) have the management capability and adequate financial and technical resources, given those that would be made available through the grant or cooperative agreement, to execute the program of activities envisioned under the grant or cooperative agreement; (2) have a satisfactory record of executing such programs or activities, if it is a prior recipient of an award; (3) have a satisfactory record of integrity and business ethics; and (4) be otherwise qualified and eligible to receive a grant or cooperative agreement under applicable laws and regulations, as outlined in part 22.420(c) of the DoDGARs, 32 CFR 22.420(c), Pre-Award Procedures.

The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism.

The DHA utilizes SAM.gov to identify individuals and organizations unqualified to receive federal awards. Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold as defined in 2 CFR 200.1, Definitions, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.gov.

B. J-1 Visa Waiver

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

Additional information on J-1 Visa Waivers can be located at the U.S. Department of State website.

C. Post-Employment Restrictions

There are certain post-employment restrictions on former federal officers and employees as defined in 18 USC 207, the Departmental Ethics Office Quick Guide. Post-employment restrictions may exist if a former federal officer or employee participates in the proposed project; the situation should be addressed with the Office of the Staff Judge Advocate at Fort Detrick prior to expending time and effort in preparation of an application.

APPENDIX 2.
FORMATTING GUIDELINES

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

- **Document Format:** Each attachment to the full application forms must be uploaded as an individual file in the format specified in the program announcement. Ensure PDF files are searchable and contain real text characters that can be recognized by standard search functions. ***Use of PDF portfolios is discouraged.*** All contributors to the application must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application components. The use of different software versions will result in corruption of the submitted file.

- **Font Size:** 11 point or larger, not condensed

- **Font Type:** Arial

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

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

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

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

- **Color, High-Resolution and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution or multimedia objects (e.g., MPEG, WAV or AVI files) embedded in the PDF file; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bitmap (BMP) and TIFF formats are not allowed. Please note that these types of objects are not allowed in the technical and public abstracts.

- **Scanning:** Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your application for agency analysis and reporting. If scanning is necessary to produce PDFs (e.g., letters of support), scanning resolution must be 100 to 150 dots per inch and the produced PDF should be searchable.

- **Security Features:** Disable all security features in your PDF documents. Do not encrypt or password protect your documents. Using these features to protect your documents also prevents us from opening and processing them.

- **Internet URLs:** URLs, or web addresses, directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.

- **Language:** All documents must be submitted in English, unless otherwise specified in the program announcement (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

APPENDIX 3.
APPEALS AND INQUIRY REVIEW PROCESS

Although not required by law or assistance regulation, the CDMRP offers the Inquiry Review Process (IRP) as a courtesy to all applicants to the CDMRP funding opportunities and other DHA funding opportunities administered by the CDMRP to maintain the high integrity of its review processes. If an application is not recommended for funding and the applicant believes a factual or procedural error occurred during the review of the application, the organization or PI may submit an inquiry through the eBRAP Help Desk at help@eBRAP.org within 15 business days after the notification letter is sent. Inquiries submitted after 15 business days will not be considered.

To be considered, the inquiry must identify and address a specific perceived factual or procedural error, as defined below:

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

- Procedural Error: An error in the review (peer or programmatic) that is restricted to review process adherence. The review process did not follow the procedures in the program announcement that describe peer and programmatic review (e.g., documents requested in the program announcement and submitted with the original application were inadvertently left out of the peer or programmatic review package).

The purpose of the IRP is to assess whether an error occurred during application review and whether the error was consequential to the programmatic funding decision. Inquiries that provide a point-by-point rebuttal to multiple weaknesses in the summary statement without clearly identifying and addressing specific perceived factual or procedural error(s) in the review will not be considered. Inquiries that misrepresent comments in the summary statement or notification letter, such as not referencing the full text of a comment or changing the language of a comment, will also not be considered.

A CDMRP IRP panel will determine whether an error occurred in either peer or programmatic review and, if so, recommend corrective action when appropriate.

The determination of an error in the review process is not a guarantee of re-review or funding.

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

APPENDIX 4.
USE OF DOW OR U.S. DEPARTMENT OF VETERANS AFFAIRS RESOURCES

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

For clinical research or trials proposing inclusion of military populations for research, see the guidance document A Primer for Conducting Department of Defense (DOD) Funded Human Research With Military Populations on the CDMRP website.

APPENDIX 5.
RESEARCH BIOSAFETY REQUIREMENTS

Safety and Environment Requirements: In certain instances, safety and environment compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include the use of DOW-provided infectious agents or toxins, select biological agents or toxins, specific chemical agent(s) or pesticides outside of an established laboratory. ***Applicants do not need to address these requirements in the initial application*** unless instructed otherwise in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding.

Additional resources are available on the U.S. Army Medical Research and Development Command (USAMRDC) Safety and Environmental Resources page.

If applicants have questions, they may contact the Surety and Environmental Manager at 301-619-2004.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: For research that is recommended for funding involving recombinant or synthetic nucleic acid molecules, the recipient must assure that all work will be in compliance with guidance provided in the NIH Office of Science Policy's NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Dual Use Research of Concern (DURC): For research that is recommended for funding that can be reasonably anticipated to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel or national security, the recipient must assure that the work will be performed in compliance with the United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern with appropriate reporting and oversight.

More information is available on the DURC policy and oversight page.

APPENDIX 6.
RESEARCH PROTECTIONS REVIEW REQUIREMENTS

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

Organizational protocol approvals (e.g., Institutional Animal Care and Use Committee [IACUC] or Institutional Review Board [IRB] approval) are not required at time of application submission, unless otherwise noted in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding. Applicants are encouraged to review the Guide for Funded Investigators and the other referenced websites below for additional information about post-award processes and requirements.

Additional information is available online.

Animal Care and Use Review Office

All DOW-funded research involving new and ongoing research with animals must be reviewed and approved by the DHA R&D ORRC Animal Care and Use Review Office (ACURO), in addition to the local IACUC of record, prior to using DOW funds to start work with animals. This includes reviewing and approving amendments to ongoing projects that will use DOW funds. When requested, PIs must submit the institutionally approved animal use protocol specific to the DOW funded work, documentation of IACUC approval of that protocol, and the completed ACURO Appendix. ACURO will only accept IACUC protocols that are directly aligned with and limited to the scope of research funded by the DOW. PIs should ***allow two to three months for the ACURO review and approval processes.***

Site Visits: The ACURO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the DHA R&D as a part of their responsibility to protect animals in research. The ACURO cannot travel to any country that is designated as Level 4 (Do Not Travel) or as a foreign country of concern by the U.S. Department of State; ***therefore, they are unable to approve animal studies proposed in those areas.*** The ACURO will consult with DHA R&D Headquarters for any country that is designated as Level 3 (Reconsider Travel) by the U.S. Department of State or DOW. The term “foreign country of concern” means the People’s Republic of China, the Democratic People’s Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the U.S. Department of State, as defined in 42 USC 19221(a)(1), Foreign Country of Concern. ***Due to these restrictions, applicant organizations should not propose to subaward, utilize contracting research organizations or collaborate with investigators performing animal studies in any country that is designated as Level 4 (Do Not Travel) or a foreign country***

of concern by the U.S. Department of State. Any application selected for award proposing animal studies in a restricted country will be required to modify their request during award negotiations. If an applicant is unable to modify the subaward, contracting research organization, or collaborator within the original budget amount requested, their selection for funding will be ***forfeited***.

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

Questions regarding ACURO should be directed to (usarmy.detrick.medcom-usamrdc.other.acuro@health.mil).

Office of Human Research Oversight

All DOW-funded research involving new and ongoing research with human subjects, data, specimens and/or cadavers must be reviewed and approved by the DHA R&D ORRC, Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee review. PIs should ***allow up to three months to complete the OHRO regulatory review and approval process following submission of all required and complete documents to the OHRO.*** Studies taking place in international settings may require additional time for completion of OHRO reviews.

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

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

A. Human Subjects Research

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

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protections Federalwide Assurance (FWA) or DOD Assurance (Intramural DOW institutions only).
- **Informed Consent Language:** The following must appear in the consent form:
    - A statement that the DOD is providing funding for the study.
    - A statement that representatives of the DOD are authorized to review research records.
    - In the event that Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom protected health information may be disclosed.

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

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

- **10 USC 980 Waiver:** If the applicant proposes to conduct a clinical trial engaging trauma patients or other planned emergency research under 21 CFR 50.24, Exception From Informed Consent Requirements for Emergency Research, which outlines provisions for an exception from informed consent, the applicant should plan for three to six months of additional time for the ORRC OHRO to review the submission and request DOW approval of a waiver of the requirements of 10 USC 980.

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

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

Detailed guidance and instructions on OHRO review of DOW-funded research activities involving access, use and analysis of human data and/or human anatomical substances is provided in the document Guidance on OHRO Review Requirements for Research Involving the Secondary Use of Data/Specimens. This guidance document also includes a detailed discussion on the types of human data, cell lines, specimens, etc., that do not require OHRO review and approval.

C. Use of Unique or Regulated Sample Types

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

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

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

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

Research Involving Use of Human Embryos: Per DoDI 3216.02, funds cannot be used to support or be used for the creation of a human embryo or embryos for research purposes (to include gene editing research); or for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury or death greater than that allowed for research on fetuses in utero, in accordance with 45 CFR 46.204(b), Research Involving Pregnant Women or Fetuses; and 42 USC 289g(b), the Risk Standard for Fetuses Intended to Be Aborted and Fetuses Intended to Be Carried to Term to Be Same.

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

RDT&E, education, or training activities involving use of human cadavers or human anatomical substances obtained from cadavers (postmortem samples) shall not begin until the DHA R&D ORRC grants approval. **Additional requirements apply to use of cadaveric specimens obtained from outside of the United States and activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces.** Additional details regarding the submission requirements for cadaver use may be requested by emailing dha.detrick.mrdc.mbx.oharo@health.mil.

E. Large-Scale Genomic Data Collected from DOW-Affiliated Personnel

Disclosure of DOW-affiliated personnel's large-scale genomic data (LSGD) may pose a national security risk; accordingly, such research (including the secondary use or sharing of identified or de-identified data or specimens) requires inclusion of administrative, technical and physical safeguards commensurate with risk. LSGD efforts must undergo security review and additional approvals by the ORRC, DHA R&D Headquarters, and DOW Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical and physical safeguards. These requirements do not apply to incidental participation of DOW-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes or phenotypes that are non-large-scale. DOW-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOW civilians and DOW contractors. DOW-funded research involving LSGD collected from DOW-affiliated

personnel may require that the performer obtain an NIH Certificate of Confidentiality. If selected for funding, performers must take these additional requirements into consideration when developing timelines and milestones.

F. Additional Information/Requirements

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

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

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

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

Site Visits: The OHRO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the DHA R&D as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner to protect the confidentiality of subject information.

Research Involving U.S. Food and Drug Administration-Regulated Products: Research evaluating the safety or effectiveness of drugs, devices, or in vitro diagnostics that are regulated by the U.S. Food and Drug Administration (FDA), requires IRB review in accordance with 21 CFR 50, Protection of Human Subjects; 21 CFR 56, Institutional Review Boards; 21 CFR 312, Investigational New Drug Application; and/or 21 CFR 812, Investigational Device Exemption, as applicable.

Clinical Trial Registry and Data Upload: The CDMRP requires all funded clinical trials to register on ClinicalTrials.gov and submit study results. When entering study identification information, include the eBRAP log number as a Secondary ID for the study with the following designation: “CDMRP-eBRAP Log Number” (e.g., CDMRP-PC26####). Ensure that “Congressionally Directed Medical Research Programs (CDMRP)” is entered as a collaborator for the study due to their role as a funding source. Additional instructions for registering a clinical trial are available at the ClinicalTrials.gov Help Resources page.

Performers conducting phase 3 clinical trials must submit results of analyses of group differences on the basis of sex, race and/or ethnicity to ClinicalTrials.gov at the time of final

report submission. If final analyses of sex, race and/or 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 the DHACA.

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

APPENDIX 7.
ADMINISTRATIVE INFORMATION

A. CDMRP Review Processes

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905, Disclosure of Confidential Information Generally.

B. Disclosure and Marking of Proprietary Information

Do not include proprietary information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation. Applicants should conspicuously and legibly mark any proprietary information that is included in the full application.

All applications recommended for funding will be subject to public release under the Freedom of Information Act (FOIA), to the extent that they are incorporated in an award document. Applications that are not selected for funding will not be subject to public release.

C. Classified Information, Data or Outcomes

In accordance with 32 CFR, Part 2002, Controlled Unclassified Information (CUI), the inclusion of classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, is disallowed and may result in application withdrawal. Classified is defined as information that has been determined pursuant to Executive Order 13526, Classified National Security Information, to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form (to include electronic copies).

D. Sharing of Application Information

The CDMRP shares application information 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 CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, coordination is enhanced and duplication of effort can be avoided, maximizing the impact of federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products and procedures to improve human health. Updates on CDMRP-funded awards, including awardee

information and published results, are shared on the Defense Technical Information Center (DTIC).

E. DOW Data Management Plan

If recommended for funding, a data management plan will be requested. DOW Data Management Plans have specific basic requirements, as described in Enclosure 3, Section 3.c. in DoDI 3200.12, the DoD Scientific and Technical Information Program (STIP); therefore, applicants should not simply upload a copy of the NIH Data Management and Sharing Plan. ***Do not duplicate the Sharing Plan.*** The DOW Data Management Plan should be no more than two pages and should include but is not limited to:

- The types of data, software and other materials to be produced
- How the data will be acquired
- Time and location of data acquisition, if scientifically pertinent
- How the data will be processed
- The file formats and the naming conventions that will be used
- A description of the quality assurance and quality control measures during collection, analysis and processing
- A description of dataset origin when existing data resources are used
- A description of the standards to be used for data and metadata format and content
- Appropriate timeframe for preservation

The plan may consider the balance between the relative value of data preservation and other factors, such as the associated cost and administrative burden. The plan will provide a justification for such decisions. ***Include a statement that the data cannot be made available to the public when there are controlled unclassified information concerns (e.g., "This data cannot be cleared for public release in accordance with the requirements in DoDI 5230.09.").***

F. Pre-Award Meeting

At the government's discretion, the PI and other personnel may be requested to participate in a pre-award meeting at the government's expense.

G. Post-Award Organization and PI Changes

Awards are made to eligible ***organizations***, not to individuals.

Transfer of Award to New Organization: Unless restricted by the specific program announcement, a change in organizational affiliation will be considered on a case-by-case basis. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. Transfers often take six months or longer; extended

times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a clinical trial at its location. Organization transfers are not allowed in the last year of the original performance period or any extension thereof.

Change in PI: Unless restricted by the specific program announcement, changes in PI will be considered on a case-by-case basis.

H. FOIA Requests

Under 5 USC 552, Public Information; Agency Rules, Opinions, Orders, Records and Proceedings, the FOIA provides a statutory basis for public access to official government records. The definition of records includes documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the FOIA.

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

I. Information Release

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

The following statements must be included in all information releases:

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

"This work was supported by the Defense Health Agency through the CDMRP (*insert program name*) under Award No. (HT942527XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the DHA."

(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.

(3) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving Recombinant or Synthetic Nucleic Acid Molecules."

(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.”

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

J. Property and Equipment

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, nonprofit, and for-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the government. However, if the award is subsequently transferred to a new organization, the DOW reserves the right to require the transfer of equipment acquired with the award funds to the federal government or to an eligible third party.

K. Title to Inventions and Patents

In accordance with 35 USC 200 et seq., the Bayh-Dole Act, the recipient and collaborators may elect to retain title to their subject inventions, subject to meeting the reporting and patent filing requirements and retained rights to the U.S. government. The U.S. government shall, at a minimum, retain nonexclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed. Additional information is available in 2 CFR 200.315, Intangible Property.

APPENDIX 8.
NATIONAL POLICY REQUIREMENTS

A. Certification

Accuracy of Current and Pending Support Documentation: The applicant, by checking "I Agree" on the SF424 (R&R) block 17, agrees 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) the PI and other key personnel 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.

Disclosure of Lobbying Activities: Certification of compliance with the national policy requirement regarding lobbying activities is required from all recipients of awards over $100,000. Submission of this certification is required by 31 USC 1352, Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions; and is a prerequisite for making or entering into an award over $100,000. Complete the SFLLL form, if applicable, and attach it to Block 18 of the SF424 (R&R) Form.

B. Representations

Required Representations: Corporations must disclose any unpaid federal tax liabilities and/or conviction of felony criminal violations under any federal law. The Required Representations form for completion and submission is available on eBRAP. Upload the form into Grants.gov under Attachments.

Representation Regarding the Prohibition on Using Funds Under Grants and Cooperative Agreements With Entities That Require Certain Internal Confidentiality Agreements: In accordance with DOW appropriations, the following representation is required. The applicant, by its signature on the SF424 (R&R) Form, represents:

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

C. National Policy Requirements

The recipient must comply with the following National Policy Requirements. Awards will incorporate the most recent set of National Policy Requirements available at the time of award.

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements
- FY21 National Defense Authorization Act, Section 223(a), and 18 USC 1001
- FY24 National Defense Authorization Act, Sections 1223 and 1224
- FY25 National Defense Authorization Act, Section 211

APPENDIX 9.
REPORTING REQUIREMENTS

If an application is recommended for funding, there are several types of reports that may be required per the terms and conditions of the specific award. The award document will specify the nature and frequency of reports (i.e., financial, technical, annual, quarterly, etc.). All awards will require, at a minimum, annual and final technical reports. Detailed descriptions of the reporting requirements are available on the USAMRDC Technical Reporting Requirements page.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

Details regarding Financial Reporting requirements are incorporated by reference into assistance agreements, with the DHACA Terms and Conditions. More general financial information is also incorporated by reference into assistance agreements and is available in the DOD Research and Development General Terms and Conditions. Organizational representatives and PIs should be sure to refer to the terms and conditions that are specific to the fiscal year in which their assistance agreement is issued.

APPENDIX 10.
DOW AND VA WEBSITES

Air Force Office of Scientific Research

Air Force Research Laboratory (ARFL)

Armed Forces Radiobiology Research Institute (AFRRI)

Congressionally Directed Medical Research Programs (CDMRP)

Defense Advanced Research Projects Agency (DARPA)

Defense Health Agency Research and Engineering Directorate

- Science and Technology Enterprise Integration Division
- Research Support & Implementation Division

Defense Health Agency Military Health System Centers of Excellence

- Consortium for Health and Military Performance
- Defense and Veterans Center for Integrative Pain Management
- Extremity Trauma and Amputation Center of Excellence
- Hearing Center of Excellence
- Joint Trauma System
- Murtha Cancer Center
- National Intrepid Center of Excellence
- Psychological Health Center of Excellence
- Traumatic Brain Injury Center of Excellence
- Vision Center of Excellence

Defense Health Agency Public Health Centers

Defense Suicide Prevention Office (DSPO)

Defense Technical Information Center (DTIC)

Defense Threat Reduction Agency (DTRA)

Military Health System Research Symposium

Navy Bureau of Medicine and Surgery

Naval Health Research Center

Naval Medical Research Command

Naval Research Laboratory

Office of Naval Research

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics

Uniformed Services University of the Health Sciences (USUHS)

U.S. Army Combat Capabilities Development Command (DEVCOM)

U.S. Army Medical Research and Development Command (USAMRDC)

USAMRDC Subordinate Commands

- U.S. Army Aeromedical Research Laboratory (USAARL)
- U.S. Army Institute of Surgical Research (USAISR)
- U.S. Army Medical Materiel Development Activity (USAMMDA)

- U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
- U.S. Army Research Institute of Environmental Medicine (USARIEM)
- U.S. Army Telemedicine and Advanced Technology Research Center (USATATRC)
- Walter Reed Army Institute of Research (WRAIR)

U.S. Army Research Laboratory

U.S. Army Sharp, Ready and Resilient Directorate

U.S. Department of Defense Blast Injury Research Coordinating Office

U.S. Department of Veterans Affairs, Office of Research and Development

U.S. Department of Veterans Affairs Health Systems Research

APPENDIX 11.
DEFINITION LIST

Adobe Acrobat Reader: Software for standard viewing, printing, signing, sharing and annotating PDF files.

Administrative Rejection: Removal of an application from consideration for funding because it meets the rejection criteria in the program announcement. Identified after submission during compliance review.

Administrative Withdrawal: Removal of an application from consideration for funding because it meets the withdrawal criteria in the program announcement. May be identified at any point following submission.

Animal Care and Use Review Office (ACURO): A component of the DHA R&D Office of Research and Regulatory Compliance (ORRC) that oversees implementation of DOD policies regarding use of animals in research, development, testing, evaluation and training.

Appropriation: A sum of money devoted to a special purpose. Appropriations for the CDMRP are added by Congress to the annual DOD budget. Funding of the CDMRP is not part of the President's budget request.

Assistance Agreement: As defined in 31 USC 6301-6308, the Federal Grant and Cooperative Agreement Act of 1977, an assistance agreement is a funding instrument through which the federal government furnishes assistance to a recipient. An assistance 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.

Award Document: The document signed by the Grants Officer authorizing the government to obligate funds to an extramural organization.

Award Mechanism: The means by which the CDMRP programs solicit high-priority research. Award mechanisms may vary by intent, target audience, the stage of the science or other characteristics. Each CDMRP program tailors award mechanisms to their individual requirements. "Award mechanism" may be used interchangeably with the term "funding opportunity."

Blinded Award Mechanism: An award mechanism that leverages a double-blinded review approach in which identifying information related to the application Principal Investigator (PI), collaborator(s) and their organization(s) are not provided to reviewers.

Budget Justification: A clear explanation for each item in the budget over the entire period of performance with sufficient detail for the government to determine whether the proposed costs are allowable, allocable and reasonable for the proposed research.

Broad Agency Announcement (BAA): A type of notice of funding opportunity (NOFO) employed by the CDMRP to provide information regarding available funds to support research grants, contracts, cooperative agreements and/or other transactions. In accordance with FAR

35.102 ,Broad Agency Announcement, projects funded under a BAA must be for applied research not related to the development of a specific system or hardware procurement.

Clinical Trial: As defined in 32 CFR 219.102, Definitions, a clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness and/or efficacy outcome(s) of an intervention do not meet the definition of a clinical trial. Additionally, studies that retrospectively analyze data generated from previously conducted clinical trial(s) are not considered clinical trials.

Clinical Research: For the purposes of the CDMRP funding opportunities, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease; (b) diagnostic or detection studies (e.g., biomarker or imaging); (c) health disparity studies; and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do ***not*** seek to assess the safety, effectiveness and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of a clinical trial.

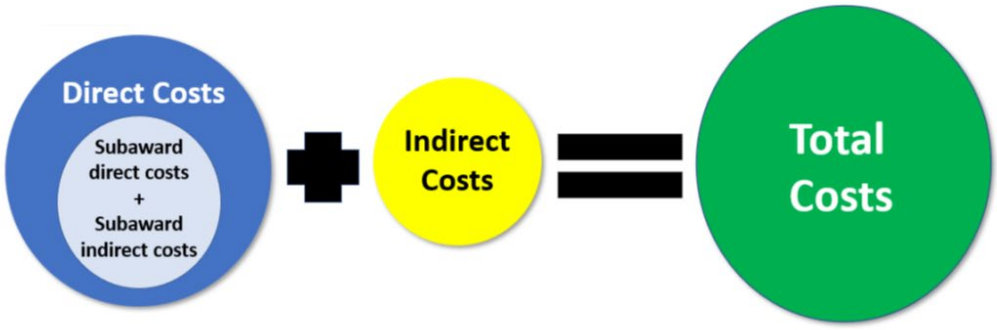
Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under 45 CFR 46.104(d)(4) of the Common Rule, Secondary Research for Which Consent is Not Required.

Contract: A funding instrument through which the executive agency, the CDMRP, aims to acquire property or services for the direct benefit or use of the U.S. government. Refer to 31 USC 6303, Using Procurement Contracts and Grant and Cooperative Agreements.

Contracting Organization: A recipient organization that is financially responsible for the award supporting the proposed research. This organization may be different from the organization where the proposed research project will be conducted (i.e., the performing organization).

Cooperative Agreement: A type of assistance agreement in which the CDMRP will have substantial involvement in assisting, guiding, coordinating and/or participating in project activities.

Cost Cap: The maximum cost allowable for a proposed research budget.



Direct Cost: The total costs for personnel salary, equipment, travel, participant/trainee support costs, materials and supplies, publications, consultant services, data processing/computer services, subaward/consortium/contractual costs, equipment or facility rental/user fees, alterations and renovations, as well as other expenses specifically associated with the proposed research project.

Department of Defense Grant and Agreement Regulations (DoDGARs): The DOD regulations that provide uniform policies and procedures for the award and administration of DOD awards.

Defense Health Agency Contracting Activity (DHACA): The DHACA is the contracting and assistance agreement element of the DHA R&D, MRDC. Items that fall under the purview of the DHACA include but are not limited to: issuing solicitations, negotiating costs, terms and conditions; issuing awards; overseeing award administration; processing award modifications and managing the award closeout process.

Electronic Biomedical Research Application Portal (eBRAP): A secure web-based system that allows PIs and/or organizational representatives to submit pre-application materials, view and verify extramural full applications submitted to Grants.gov, receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. Intramural organizations may also submit full applications through eBRAP following pre-application submission.

Extramural Organization: A foreign or domestic non-DOW organization. Examples of extramural organizations include, but are not limited to, academic institutions, biotechnology companies, foundations, federal government organizations other than the DOW (i.e., intragovernmental organizations) and research institutes.

Extramural Submission: An application submitted through Grants.gov by an extramural organization or intramural organization.

Foreign Country of Concern (FCOC): As defined in Public Law 117-167-Aug. 9, 2022 Section 10638, the term ‘‘foreign country of concern’’ means the People’s Republic of China, the Democratic People’s Republic of Korea, the Russian Federation, the Islamic Republic of Iran, or any other country determined to be a country of concern by the Secretary of State.

Full Application: A completed application package including all required forms and attachments as described in the NOFO. The CDMRP staff and contractors will review full application materials to ensure compliance with NOFO requirements and administrative/national policies prior to making funding recommendations.

Funding Authorization Document (FAD): The means by which funds may be distributed and apportioned as necessary to certain military services and defense agencies.

General Application Instructions (GAI): A document to be read in conjunction with the program announcement that provides additional details and instructions for application preparation and submission. The program announcement provides the basic information necessary to prepare an application (i.e., what to submit); whereas the GAI provides additional details and instruction for both application preparation and submission (i.e., how to submit).

Grant: A type of assistance agreement in which the CDMRP is not anticipated to have substantial involvement beyond standard award monitoring and management.

Grants.gov: An e-government system that provides a centralized location for grant seekers to find and apply for federal funding opportunities being openly competed.

Indirect Costs: The indirect costs may include facilities and administrative, overhead, general and administrative, and other costs. The most recent federal agency-approved rate(s) should be applied in the application budget. No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate. Organizations can also visit the websites for the DHHS, the Office of Naval Research and the Defense Contract Audit Agency for additional information on indirect rates.

Initiating PI: The term used to describe the individual investigator who will be responsible for most of the administrative tasks associated with application submission. This term is specific for NOFOs that allow for multiple PIs.

Institutional Animal Care and Use Committee (IACUC): A committee required by federal regulations for most institutions that use animals in research, testing and teaching. The committee has an oversight role including the review and approval of animal use activities and inspection of animal facilities.

Institutional Review Board (IRB): An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The IRB has the authority to approve, require modifications in or disapprove all research activities that fall within its jurisdiction.

Interim (In-Progress) Review (IPR): An IPR meeting may be held during an award's period of performance to monitor the progress of the award and evaluate its status.

Intervention: Includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Intragovernmental Organization: Any U.S. federal government organization.

Intramural DOW Organization: A subset of intragovernmental organizations; refers specifically to DOW organizations, including DOW laboratories, DOW military treatment facilities, and/or DOW activities embedded within a civilian medical center.

Intramural Submission: An application submitted through eBRAP by a DOW organization for an intramural investigator working within a DOW laboratory or military treatment facility or in a DOW activity embedded within a civilian medical center.

Knowledge Product: A non-materiel product that addresses an identified need, topic area or capability gap; is based on current evidence and research; aims to transition into medical practice, training or tools or to support materiel solutions (systems to develop, acquire, provide and sustain medical solutions and capabilities); and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.

Letter of Intent (LOI): A type of pre-application used for program planning purposes only. An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop the LOI and full application components concurrently and submit a full application AFTER successful submission of the ***required*** LOI. Full applications that are submitted without an LOI being submitted by the posted deadline will be rejected.

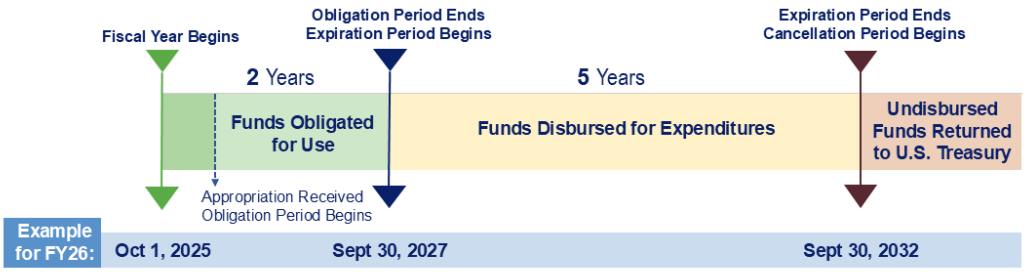
Malign Foreign Talent Recruitment Program: The complete definition of "malign foreign talent recruitment program" is available within Public Law 117-167-Aug. 9, 2022 Section 10638.

Military Interdepartmental Purchase Request (MIPR): A method for transferring funds by one military organization to another.

Military Treatment Facility: Hospitals or clinics within the Military Health System located at military bases and ports around the world.

Notice of Funding Opportunity (NOFO): A publicly available document by which the CDMRP, in partnership with the contracting authority, DHACA, makes known the availability of funds and solicits research that meets the intent of a given award mechanism. The CDMRP leverages two types of NOFOs: program announcements and broad agency announcements.

Obligation Deadline: RDT&E funding must be obligated within 24 months from the start of the fiscal year in which the funds were appropriated. Obligating funds commits funds to a specific award or purpose. After the 24-month obligation window, obligated funding will be available for another five years for disbursement to the award recipient. Undisbursed funds are returned to the U.S. Treasury at the end of the five-year expiration period.



Office of Human Research Oversight (OHRO): A component of the DHA R&D ORRC that oversees implementation of DOD policies regarding use of involving human subjects, human data and/or anatomical substances in research, development, testing, evaluation and training.

Office of Research and Regulatory Compliance (ORRC): The office within the DHA R&D, MRDC that ensures CDMRP-funded research involving human subjects, human data and/or anatomical substances, or animals are conducted in accordance with federal and international regulatory requirements. The ORRC has three major subordinate offices: the ACURO; the OHRO; and the IRB Office.

Open Researcher and Contributor ID (ORCID): A unique, open digital identifier that distinguishes the individual from every other researcher with the same or a similar name.

Other Transaction: A funding instrument other than a contract, cooperative agreement or grant issued by the federal government to enable a recipient to carry out certain research, prototype and production projects in accordance with 10 USC 4021, Research Projects: Transactions Other Than Contracts and Grants; and 10 USC 4022, Authority of the Department of Defense to Carry Out Certain Prototype Projects.

Partnering PI: This term is specific to program announcements that offer an option of separate awards to multiple PIs for a single project. The term describes other PI(s) who will work in collaboration with an initiating PI to execute a research project. As a separate awardee, a Partnering PI is more than a co-investigator or typical "key personnel." Partnering PIs have their own administrative responsibilities when it comes to application submission and fulfilling post-award requirements, and are expected to contribute significantly to the development and execution of the proposed research project. Partnering PIs are required to register in eBRAP, associate the pre-application submitted by the initiating PI with their account, and submit an abbreviated full application package as instructed in the program announcement, if applicable.

Peer Review: The first tier in the CDMRP's two-tier review process, involving the evaluation of applications against established criteria outlined in each NOFO to determine technical merit, where each application is assessed for its own merit, independent of other applications.

Period of Performance: The time interval between the start of a federal award and the planned end date.

Performing Organization: Site/organization at which the proposed research will be conducted. This organization may be different from the organization financially responsible for the award (i.e., the contracting organization).

Pre-Application: The first step in the CDMRP's two-step application process, submitted through eBRAP. The CDMRP utilizes two types of pre-applications: Letter of Intent ***or*** Preproposal.

Preproposal: A type of pre-application that undergoes pre-application screening against review criteria specified in the NOFO. Following the pre-application screening, PIs will be notified as to whether they are invited to submit full applications. Applicants must have an invitation to submit a full application. Uninvited full application submissions will be rejected.

Program Announcement: A funding opportunity announcement that solicits grant or cooperative agreement applications by providing the basic information necessary to prepare an

application for federal funding; detailed submission instructions are included in the associated GAI.

Programmatic Review: The second tier in the CDMRP's two-tier review process; a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance according to criteria outlined in each NOFO.

Regulatory Agency: For the purposes of the CDMRP's funding opportunities, Regulatory Agency refers to the U.S. Food and Drug Administration or any equivalent international regulatory agency.

System for Award Management (SAM): An official website of the U.S. government used to register to do business with the U.S. government; update, renew or check the status of your entity registration; search for entity registration and exclusion records; search for assistance listings, wage determinations, contract opportunities and contract data reports; view and submit BioPreferred and Service Contract Reports; and access publicly available award data via data extracts and system accounts.

Total Cost: The total costs (both direct costs and indirect costs) proposed by the applicant to carry out a research project.

Unique Entity Identifier (UEI): The identifier assigned by the SAM to uniquely identify business entities.

APPENDIX 12.
ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AL	Assistance Listing (formerly, Catalog of Federal Domestic Assistance [CFDA])
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
BAA	Broad Agency Announcement
BMP	Bitmap File Format for Digital Images
CAGE	Commercial and Government Entity
CDC	U.S. Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRADA	Cooperative Research and Development Agreement
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DHHS	U.S. Department of Health and Human Services
DOD	U.S. Department of Defense
DoDI	Department of Defense Instruction
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
DTIC	Defense Technical Information Center
DURC	Dual Use Research of Concern
E-Biz	Electronic Business
eBRAP	electronic Biomedical Research Application Portal
EC	Ethics Committee
EIN	Employer Identification Number
F&A	Facilities and Administrative
FAD	Funding Authorization Document
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
FY	Fiscal Year

G&A	General and Administrative
GAI	General Application Instructions
GSA	U.S. General Services Administration
HIPAA	Health Insurance Portability and Accountability Act
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
IRP	Inquiry Review Process
JPEG	Joint Photographic Experts Group
LSGD	Large-Scale Genomic Data
MB	Megabyte
MIPR	Military Interdepartmental Purchase Request
MPEG	Moving Picture Experts Group
NCAGE	North Atlantic Treaty Organization Commercial and Government Entity
NIH	National Institutes of Health
NOFO	Notice of Funding Opportunity
NSF	U.S. National Science Foundation
NSPM-33	National Security Presidential Memorandum-33
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID
ORRC	Office of Research and Regulatory Compliance (previously Office of Human and Animal Research Oversight)
PD	Project Director
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
RDT&E	Research, Development, Test and Evaluation
RM	Resource Manager
R&R	Research & Related
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF	Standard Form
SFLLL	Disclosure of Lobbying Activities Standard Form LLL on Grants.gov
SF424 (R&R)	Application for Federal Assistance Standard Form 424 (Research & Related) on Grants.gov
SOW	Statement of Work
STEM	Science, Technology, Engineering and/or Mathematics

TIFF	Tagged Image File Format
TIN	Tax Identification Number
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs
WAV	Waveform Audio