General Submission Instructions for the Department of Defense Defense Health Program

Version CD25_01

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I. GENERAL INFORMATION

A. How to Use the General Submission Instructions

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

The following symbols are used throughout the GSI:

Marks particularly helpful or important information.

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

B. Current Funding Opportunities and Email Notifications

Funding opportunities currently offered through the U.S. Army Medical Research and Development Command (USAMRDC), including those 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 on Grants.gov. Applicants/offerors should subscribe on Grants.gov to receive official notifications of new funding opportunity postings and updates. Applicants/offerors 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/offeror to check for published updates to the funding opportunity and the application/proposal package prior to submission; the applicant/offeror is responsible for using the latest version of the full application/proposal package. If the Grants.gov application/proposal package is updated or changed, then previous versions of the application/proposal 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. Applicants/offerors 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/proposal and the full application/proposal.

C. Agency Contacts

eBRAP Help Desk: Questions related to broad agency announcement content or submission requirements, as well as questions related to submission of pre-applications/proposals, or full applications/proposals from intramural organizations, through eBRAP, should be directed to the eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern Time (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

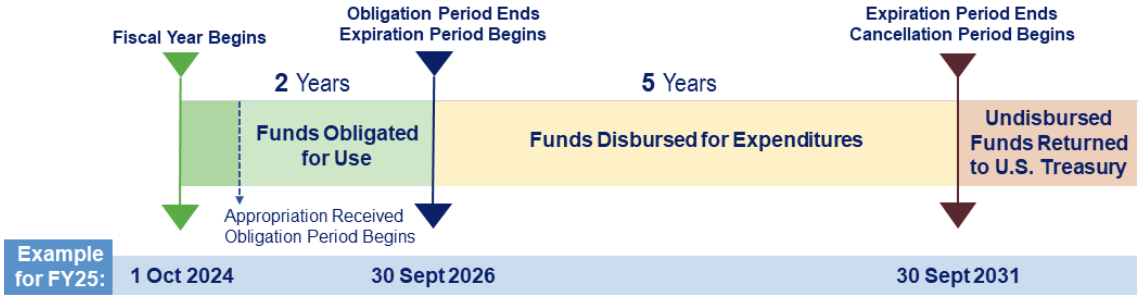
Grants.gov Support Center: Questions related to application/proposal submission through the Grants.gov portal should be directed to the Grants.gov Support Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays).

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

Email: support@grants.gov

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 2025 [FY25] funds must be obligated no later than 30 September 2026). 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., FY25 funds close for disbursement to performers 30 September 2031).



Pre-Award Costs:

Other Transaction (OT) Awards: An organization may request and negotiate pre-agreement costs with the Agreements Officer.

Contract Awards: An organization may request and negotiate pre-contract costs prior to contract award. An advanced agreement must be executed by the Contracting Officer prior to incurring any cost. Advanced Agreement Costs (Pre-Contract Costs) are referenced in Federal Acquisition Regulation, Part 31, Sections 31.205-32 (FAR 31.205-32) and Advanced Agreements in FAR 31.109.

Assistance Agreement Awards: 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 either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The government expects the 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. Eligible Applicant Organizations

Unless otherwise specified in the broad agency announcement, applications/proposals may be submitted by extramural organizations and intramural Department of Defense (DOD) organizations, defined as follows:

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

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

B. Applications/Proposals Involving Intragovernmental or Intramural DOD Organizations

To provide information specific to intragovernmental and intramural DOD investigators contributing to the submission of an application, the CDMRP developed a Guide for

Intragovernmental and Intramural DOD Applicants. Applicants are recommended to reference this guide for additional information and considerations unique to intragovernmental and intramural organizations.

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

The USAMRDC's RM office will "direct fund" Intragovernmental/Intramural DOD 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 DOD organizations. The USAMRDC RM 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 DOD Organization: Direct transfer of funds from any extramural award recipient to an intragovernmental or intramural DOD organization is not allowed except under very limited circumstances. As noted above, funding of intragovernmental or intramural DOD organizations, including research collaborators, will be managed through a direct funds transfer from the USAMRDC's RM office.

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 DOD 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/proposal submission. A timeline for execution of the CRADA should be included within the project's Statement of Work (SOW).

C. Pre-Application/Proposal and Full Application/Proposal Submission Portal Systems

The 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/proposals. Intramural DOD organizations may submit full applications/proposals through eBRAP.

Additionally, the eBRAP system allows a submitting organization's representatives and PIs to view and modify certain components of the full application/proposal submission package(s) during a specified verification period. eBRAP validates full application/proposal files against the specific broad agency 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/offeror's responsibility to review all application/proposal components for accuracy

and to ensure proper ordering as specified in the broad agency announcement. All verification periods are specified in the broad agency announcement.

Grants.gov is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications/proposals for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application/proposal through eBRAP. ***Extramural organizations must submit full applications/proposals through Grants.gov.***

D. Application/Proposal Submission Overview

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

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

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

> ***Grants.gov:*** Full applications/proposals from extramural organizations ***must*** be submitted through Grants.gov Workspace. Refer to Section IV, Full Application Submission through Grants.gov for application/proposal preparation and submission instructions.
>
> ***eBRAP:*** Only full applications/proposals submitted by an intramural DOD organization may be submitted through eBRAP. Refer to Section V, Full Application Submission through eBRAP for application/proposal preparation and submission instructions. Full applications/proposals from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn.

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

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

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

If the funding mechanism allows for Partnering PIs, the U.S. Army Medical Research Acquisition Activity (USAMRAA) requires separate full application/proposal package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The Partnering PI application/proposal 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/proposal package must be

submitted using the unique eBRAP log number. ***All associated applications/proposal (the Initiating PI's and Partnering PI's) must be submitted by the full application/proposal submission deadline.***

III. PRE-APPLICATION SUBMISSION

General information about eBRAP registration and pre-application/proposal 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/proposal.

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), also known as a Primary Organization Representative to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application/proposal submission deadline in order for the pre-application/proposal to be submitted. ***However, the organization's eBRAP registration must be completed before the full application/proposal submission deadline to allow for processing, viewing, and modifying select components of the full application/proposal package during the submission verification period.***

Extramural Organizations: Applicants/offerors 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 Organizations: Applicants/offerors 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/proposal package is submitted through eBRAP.

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

For specific instructions regarding content of the pre-application/proposal submission components, refer to Section 5.3.1, Pre-Application/Proposal Submission, in the broad agency announcement.

All pre-application/proposal components must be submitted through eBRAP by the deadline specified in the broad agency announcement.

To start a new pre-application/proposal, 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/proposal will be requested at this step, including application/proposal 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/proposal 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/proposal submission.

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

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

Summary Tab: This tab displays the information previously entered for the pre-application/proposal, such as application/proposal title, PI, Business Official, performing organization, contracting organization, etc. As the steps of the pre-application/proposal 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/proposal. Prepopulated information can be changed in this tab, including the application/proposal 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/proposals, 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/proposal 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/proposal deadline, but the Business Official has until the full application/proposal deadline to complete the registration. This registration is required for the Business Official to view, modify, and verify the application/proposal in eBRAP after submission.

Select the performing organization (site/organization at which the PI will perform the proposed work) and the contracting organization (recipient organization financially responsible for the award). The organization(s) must be either selected from the options available in eBRAP or invited in order for the pre-application/proposal to be submitted.

It is recommended that applicants/offerors identify an Alternate Submitter in the event that assistance with pre-application/proposal 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/proposal, 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 found to have assisted in the pre-application/proposal or application/proposal processes. Refer to the specific broad agency 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/proposal. I Includ individuals with whom the PI has a personal or professional relationship.

Tab 5 – Pre-Application Files: Upload all components as individual PDF files as specified in the broad agency announcement. Pre-applications/proposals that have components exceeding the specified page limits may be rejected, or excess pages may be deleted from the file(s). Refer to the specific broad agency announcement for detailed 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/proposal submission. ***This finalizes the pre-application/proposal submission process.***

Following completion of pre-application/proposal submission, the status of the pre-application/proposal 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/proposal is not submitted until Tab 6 is complete. Pre-applications/proposals not submitted remain in DRAFT status. An applicant/offeror with a pre-application/proposal in DRAFT status after the pre-application/proposal submission deadline is ineligible to submit a full application/proposal. There is no grace period.

IV. FULL APPLICATION/PROPOSAL 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.*** Registering early is advised.

Foreign organizations doing business outside of the United States 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/offeror 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/proposal through Grants.gov. ***All federal awards, including but not limited to contracts, grants, and cooperative agreements must use the unique entity identifier (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/proposal submission deadline.*** If your organization does not have either an Employer Identification Number (EIN) or Tax Identification Number (TIN), allow at least two weeks to receive this information from the U.S. Internal Revenue Service. ***Allow several 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/proposals 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/offeror 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. On average, CAGE code or NCAGE code validation in the SAM occurs within three business days 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/proposal package. At the time of application/proposal submission to Grants.gov, the AOR certifies that, to the best of their knowledge, all information provided in the application/proposal is current, accurate, and complete. For applications/proposals submitted through Grants.gov, the name of the AOR submitting the application/proposal is inserted into the application's/proposals 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/proposals 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/offerors, is crucial for valid and timely submissions.

4. Create Grants.gov Workspace

Applicants/offerors must create a Grants.gov Workspace, which allows the application/proposal components to be completed online and routed through the applicant/offeror 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/proposal process through Grants.gov Workspace is available on the Grants.gov How to Apply For Grants page.

Each application/proposal submission must include the completed application/proposal package of forms associated with the specific broad agency announcement in Grants.gov.

Applicants/offerors who prepare the application/proposal 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/proposals. 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/offeror'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/offeror organization using system-to-system interfaces with Grants.gov.

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

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

Additionally, the correct eBRAP log number associated with the application/proposal must be used throughout the entire submission process. Inconsistencies may delay application/proposal processing and limit or negate the ability to view, modify, and verify the application/proposal in eBRAP during the submission 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/proposal 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/proposal package must be resubmitted with the Changed/Corrected Application box selected.

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

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

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

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

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

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

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

- **Block 5 – Applicant Information.** Enter the information for the applicant/offeror 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/offeror organization.

- **Block 8 – Type of Application.** Select New for all submissions. Indicate whether the application/proposal 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/proposal.

- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application/proposal 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/offeror 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/proposal. If outside the United States, select the appropriate country from the drop-down menu.

- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget 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 award 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/offeror AOR organization's authorized representative. The Signature of

Authorized Representative is automatically completed upon submission of the Grants.gov application/proposal 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/proposal 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/proposal 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. For all attachments, ensure that the file names are consistent with the guidance in the broad agency 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/proposal package including all the attachments to 200MB.

Do not password protect any files of the application/proposal 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 the broad agency announcement. Attach each as a separate PDF file, named as indicated in the announcement.

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

- **Attachment: Project Narrative: Attach as "ProjectNarrative.pdf".** The Project Narrative is the main body of the application.
- **Attachment: Supporting Documentation: Combine and attach as a single PDF named "Support.pdf".** 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/proposal may be administratively withdrawn. ***Letters of support not requested in the broad agency announcement, such as those from members of Congress, will be removed from the application/proposal package.***

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

- **Attachment: Technical Abstract: Attach as "TechAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website. ***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.

- **Attachment: Lay Abstract: Attach as "LayAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website. ***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.

- **Attachment: 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 DOD-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/offerors are strongly encouraged to use the suggested SOW format stated in the broad agency announcement. Templates for SOW formats are available on the eBRAP Funding Opportunities and Forms page along with Examples for assembling statements of work.

- **Attachment: Suggested Intragovernmental/Intramural Budget Form, *if applicable*: Attach as "IGBudget.pdf".** If an intramural DOD organization will collaborate in the performance of the project, complete a separate Suggested Intragovernmental/Intramural Budget Form for each intramural DOD organization involved in the project and upload as a single document. Detailed instructions for completing the Suggested Intragovernmental/Intramural Budget Form are provided in Section V, Full Application Submission Through eBRAP.

C. Additional Application Materials

(a) Research & Related Personal Data

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

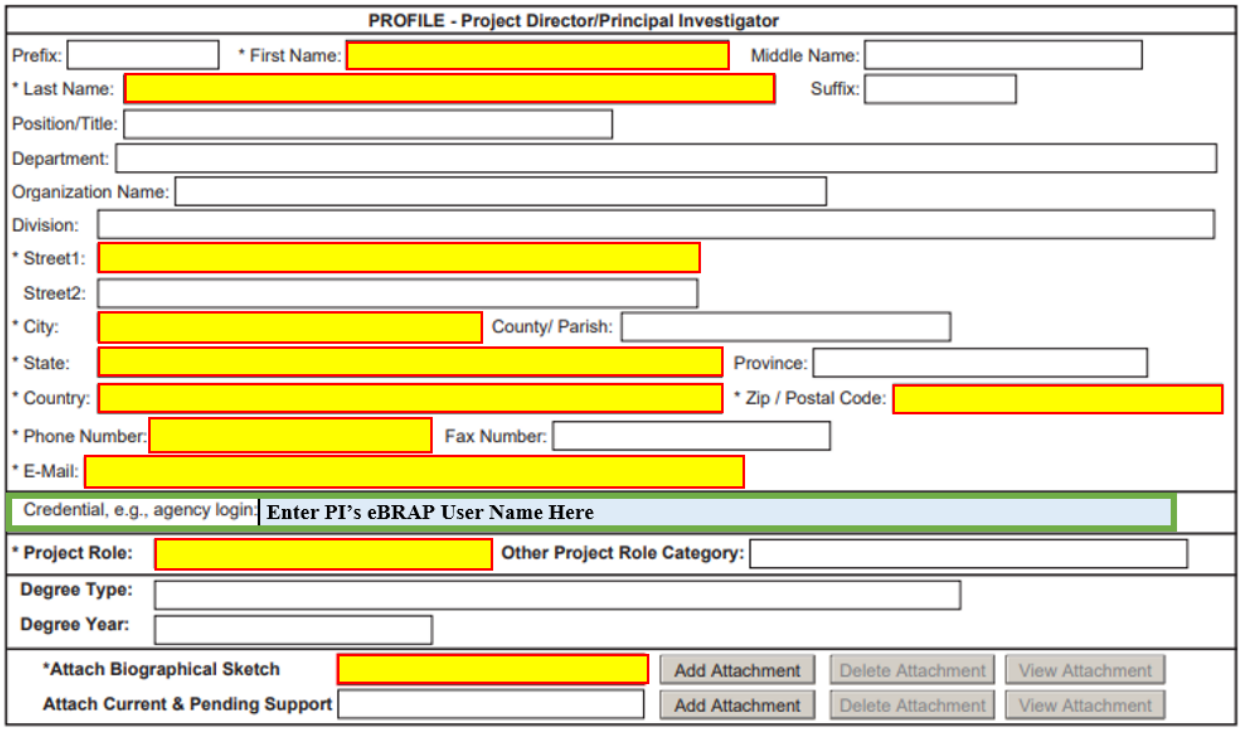
(b) Research & Related Senior/Key Person Profile (Expanded)

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/proposal

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 1). 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 1. PI’s eBRAP User Name



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

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

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

  Consistent with NSPM-33, individuals are required to disclose contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if

an individual receives direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government-sponsored or affiliated activities. In accordance with 42 USC 19232, the Malign Foreign Talent Recruitment Program Prohibition Statute, individuals are prohibited from being a party in a malign foreign talent recruitment program.

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

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

(1) Identifying Information

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

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

(iii) Position Title: Enter the current position title of the Senior/Key person.

(2) Organization and Location

(i) Name: Enter the name of the primary organization of the Senior/Key person.

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

(3) Professional Preparation

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

For each entry provide:

- the name of the organization

- the location of the organization: Enter the City, State/Province, and Country where the organization is located. If the State/Province is not applicable, enter N/A.
- the degree received (if applicable)
- the start date of the degree or fellowship program
- the month and year the degree was received (or expected receipt date)
- the field of study

(4) Appointments and Positions

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

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

For each entry provide:

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

(5) Products

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

- publications, conference papers and presentations
- website(s) or other Internet site(s)
- technologies or techniques

- inventions, patents, patent applications and/or licenses
- other products, such as data, databases, or datasets, physical collections, audio or video products, software, models, educational aids or curricula, instruments or equipment, research material, interventions (e.g., clinical or educational), or new business creation

Each product must include full citation information including:

- names of authors
- product title
- date of publication or release
- website URL
- other persistent identifier (if available)
- other relevant citation information (e.g., in the case of publications, title of enclosing work such as journal or book, volume, issue, pages)

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

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

(6) Certification

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

I certify that the information provided is current, accurate, and complete. This includes but is not limited to information related to domestic and foreign appointments and positions.

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

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

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

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

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

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

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

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

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

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

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

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

(1) Identifying Information

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

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

(iii) Position Title: Enter the current position title of the Senior/Key person.

(2) Organization and Location

(i) Name: Enter the name of the primary organization of the Senior/Key person.

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

(3) Proposals/Active Projects

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

(i) Title: Enter the title of each project/active proposal being reported.

(ii) Status of Support: Select the appropriate status type as defined below:

> Current – all active projects, or projects with ongoing obligations, from whatever source irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.
>
> Pending – any proposal that is being considered for funding from a potential funding organization (including this application/proposal) irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

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

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

(v) Primary Place of Performance: Identify the primary location where the proposal and/or active project is being executed. Enter the City, State/Province, and Country where the organization is located. If the State/Province is not applicable, enter N/A.

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

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

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

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

(x) Overall Objectives: Provide a brief statement of the overall objectives of the proposal/active project. This field is limited to 1,500 characters.

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

(4) In-Kind Contributions

In this section, disclose ALL in-kind contributions with an estimated dollar value of $5,000 or more and that require a commitment of the individual's time. An in-kind contribution is a non-cash contribution provided by an external entity that directly supports the individuals' research and development efforts. An in-kind contribution may include, but is not limited to: real property; laboratory space; equipment; data or data sets; supplies; other expendable property; goods and services; employee or student resources. In-kind contributions with an estimated value of less than $5,000 need not be reported.

(i) Status of Support: Select the appropriate status type as defined below:

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

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

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

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

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

(vi) U.S. Dollar Value of In-Kind Contribution: Enter the U.S. dollar value of the in-kind contribution with an estimated value of $5,000 or more. If the dollar value is not readily ascertainable, a reasonable estimate should be provided. If the support is in a foreign country's currency, convert to U.S. dollars at time of submission rounded to the nearest dollar.

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

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

(5) Certification

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

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

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

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

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

(c) Research & Related Budget

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 using the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs, and period of performance, refer to the broad agency 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/proposal 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/proposal package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application/proposal submission deadline.

Budget Regulations and Restrictions:

- **Administrative and Cost Principles:** Recipients will be 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/proposals in response to a broad agency announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications/proposals may be an allowable cost that can be included in the indirect/facilities and administrative (F&A) cost as specified in the organization's applicable cost principles.
- **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

number, 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 number is entered accurately or Grants.gov will reject the application/proposal.

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/offeror 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/offeror 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 and 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/proposal is recommended for funding, the organization will be required 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, indicate 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 and therefore these salaries should not be included in the requested budget.***

- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the application/proposal is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).

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

Section C: Equipment Description. Equipment is tangible personal property (including information technology systems) having a useful life of more than 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/offeror organizations are encouraged to provide all equipment necessary to conduct the proposed research project.

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

Funds to an extramural organization may not be used to cover travel costs for DOD military and civilian employees. All approved travel costs for DOD military and civilian employees will be paid by the government through a direct fund transfer. Proposed travel costs for DOD 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 limit stated in the broad agency announcement.

Section H: Indirect Costs. The indirect costs category may include 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 10% of modified total direct costs. Costs must be consistently charged as either indirect or direct costs but may not be double-charged or inconsistently charged as both. If this methodology is chosen, it must be used consistently for all federal awards until such time as the 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 effort. Applicants/offerors 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/offerors performing research outside of the United States will be determined at the time of application/proposal 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. 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 funding opportunity.

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; and include the daily consultant fee, travel expenses, nature of the consulting effort; and why consultants are required for the proposed research project.

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 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 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 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/proposals involving an intragovernmental or intramural DOD organization, include a federal financial plan in the budget justification. The plan must address how any funds transferred to the intragovernmental or intramural DOD 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 DOD 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/proposals that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations, or collaborators employed by foreign organizations/governments, are required to demonstrate how one or more of the following conditions have been met:

- The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources; and/or access to a geographic location or population not generally available to investigators based in the 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.

(d) 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.

(e) 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 DOD 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 (including the direct and indirect costs of any subawardees) should not exceed the cost limit stated in the broad agency announcement.

D. Submission to Grants.gov

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

All applications/proposals must be received by the deadline indicated in the broad agency announcement. Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application/proposal is successfully received by Grants.gov. The applicant/offeror AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the application/proposal. Applicant/offeror AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the application's/proposal'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/proposal 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 into eBRAP to review, modify, and verify the full application/proposal submission. Verification is strongly recommended but not required. eBRAP will validate full application/proposal files against the specific broad agency 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/offeror's responsibility to review all application/proposal components and ensure proper ordering as specified in the broad agency announcement.

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

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

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

V. FULL APPLICATION/PROPOSAL SUBMISSION THROUGH eBRAP

A. Content and Form of Full Application/Proposal Submission – eBRAP

(a) eBRAP Full Application/Proposal Package Components

The eBRAP full application/proposal 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 on Start Full Application** for the log number under which the pre-application/proposal was submitted.

- **Tab 1 – Summary:** Provides a summary of the application/proposal information and copies of standard application/proposal 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/proposal component in eBRAP as individual PDF files. Refer to Appendix 2 for detailed formatting guidelines.
- **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/proposal 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 broad agency announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the Confirm Submission button to complete the application/proposal submission. eBRAP will notify your RM/Comptroller/Task Area Manager or equivalent Business Official by email to login to eBRAP to review and approve the full application/proposal package prior to the approval deadline.

(b) Attachments

Application/proposal 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. Do not password protect any files of the application/proposal package, including the Project Narrative.

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 the broad agency announcement. Attach each as a separate PDF file, named as indicated in the announcement.

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

- **Attachment: Project Narrative: Attach as "ProjectNarrative.pdf".** The Project Narrative is the main body of the application.

- **Attachment: Supporting Documentation: Combine and attach as a single PDF file named "Support.pdf".** 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/proposal may be administratively withdrawn. ***Letters of support not requested in the broad agency announcement, such as those from members of Congress, will be removed from the application/proposal package.***

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

- **Attachment: Technical Abstract: Attach as "TechAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website. ***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.

- **Attachment: Lay Abstract: Attach as "LayAbs.pdf".** Abstracts of all funded research projects will be posted on the CDMRP website. ***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.

- **Attachment: SOW: 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(ies) where DOD-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 stated in the broad agency announcement. A suggested template for SOW format is available on the eBRAP Funding Opportunities and Forms page along with Examples for assembling statements of work.

B. Additional Application Materials

(a) Research & Related Personal Data

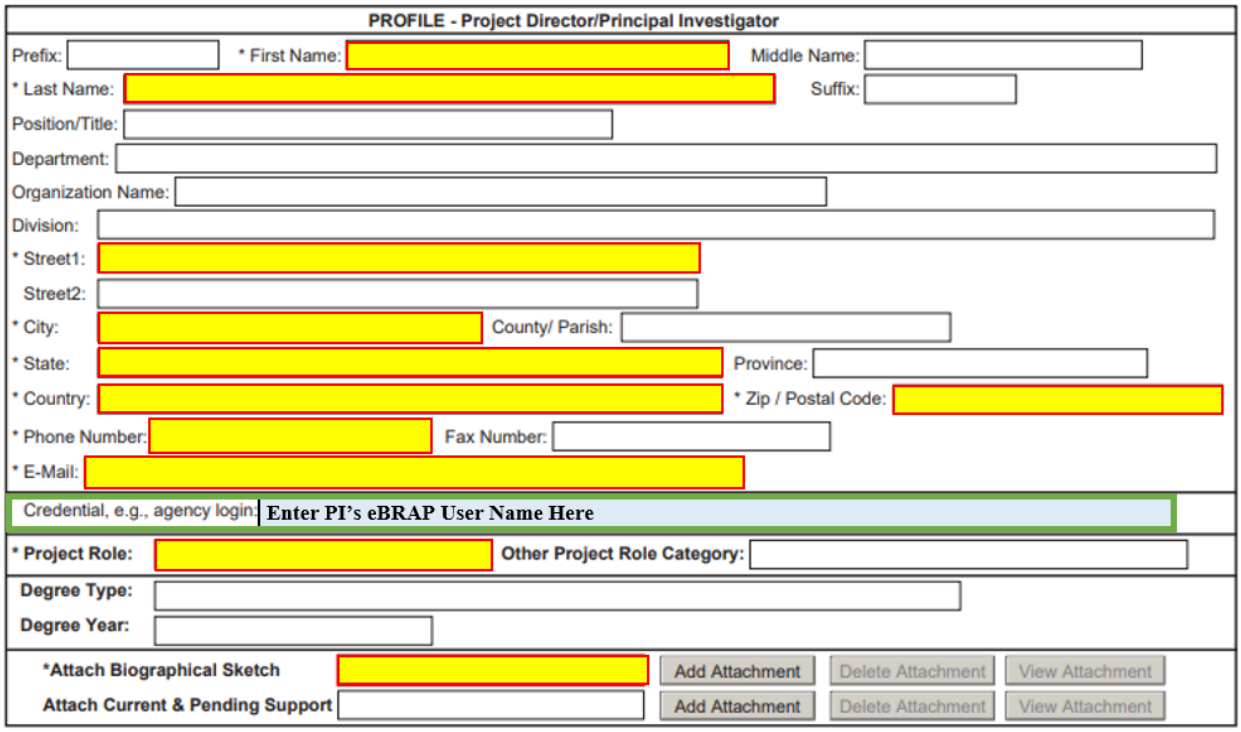
Each application/proposal must include this form with the name fields of the PD/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the Next Person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

Upload the Research & Related Personal Data Form as "PersonalData_LastName.pdf" to Tab 3 – Full Application Files.

(b) 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/proposal 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.

Figure 2. PI's eBRAP User Name



A biographical sketch and full description of each PI and Senior/Key Person's previous/current/pending support information may be either 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.

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

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

  Consistent with NSPM-33, individuals are required to disclose contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if an individual receives direct or indirect support that is funded by a foreign government-

sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government-sponsored or affiliated activities. In accordance with 42 USC 19232, the Malign Foreign Talent Recruitment Program Prohibition Statute, individuals are prohibited from being a party in a malign foreign talent recruitment program.

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

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

(1) Identifying Information

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

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

(iii) Position Title: Enter the current position title of the Senior/Key person.

(2) Organization and Location

(i) Name: Enter the name of the primary organization of the Senior/Key person.

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

(3) Professional Preparation

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

For each entry provide:

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

- the degree received (if applicable)
- the start date of the degree or fellowship program
- the month and year the degree was received (or expected receipt date)
- the field of study

(4) Appointments and Positions

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

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

For each entry provide:

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

(5) Products

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

- publications, conference papers and presentations
- website(s) or other Internet site(s)
- technologies or techniques
- inventions, patents, patent applications and/or licenses

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

Each product must include full citation information including:

- names of authors
- product title
- date of publication or release
- website URL
- other persistent identifier (if available)
- other relevant citation information (e.g., in the case of publications, title of enclosing work such as journal or book, volume, issue, pages)

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

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

(6) Certification

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

I certify that the information provided is current, accurate, and complete. This includes but is not limited to information related to domestic and foreign appointments and positions.

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

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

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

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

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

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

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

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

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

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

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

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

(1) Identifying Information

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

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

(iii) Position Title: Enter the current position title of the Senior/Key person.

(2) Organization and Location

(i) Name: Enter the name of the primary organization of the Senior/Key person.

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

(3) Proposals/Active Projects

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

(i) Title: Enter the title of each project/active proposal being reported.

(ii) Status of Support: Select the appropriate status type as defined below:

> Current – all active projects, or projects with ongoing obligations, from whatever source irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.
>
> Pending – any proposal that is being considered for funding from a potential funding organization (including this proposal) irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

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

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

(v) Primary Place of Performance: Identify the primary location where the proposal and/or active project is being executed. Enter the City, State/Province, and Country where the organization is located. If the State/Province is not applicable, enter N/A.

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

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

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

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

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

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

(4) In-Kind Contributions

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

(i) Status of Support: Select the appropriate status type as defined below:

> Current – all in-kind contributions obligated from whatever source irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.
>
> Pending – all in-kind contributions currently under consideration from potential funding organizations irrespective of whether such support is provided through the proposing organization or is provided directly to the individual.

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

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

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

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

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

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

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

(5) Certification

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

I certify that the information provided is current, accurate, and complete. This includes, but is not limited to, information related to current, pending, and other support (both foreign and domestic) as defined in 42 U.S.C. § 6605. I also certify that, at the time of submission, I am not a party in a malign foreign talent recruitment program.

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

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

(c) Budget Form

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 the eBRAP Funding Opportunities and Forms page. For limits on funding amounts, types of costs, and period of performance, refer to the broad agency 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/proposal prior to the full application/proposal submission deadline. Any additional modifications to the budget must also be completed prior to the full application/proposal 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/proposals in response to a broad agency announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications/proposals may be an allowable cost that can be included in the indirect/F&A cost as specified in the organization's applicable cost principles.
- **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 project.

DOD 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 totals are correctly auto-calculated.

- **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/offeror organizations are encouraged to provide all equipment necessary to conduct the proposed research project.

- **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/offerors are responsible for budgeting all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected

DOD per diem rates. Note, military and federal civilian travel costs, unless funded via a project order, cannot not be subjected to fees/indirect costs.

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

- **Other Direct Costs:** Itemize other anticipated direct costs such as research-related subject cost, publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Estimate the costs of publishing and reporting research results, including direct charges for clerical services, illustrations, reprints and distribution. Organizationally provided 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 limit stated in the broad agency 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 Resource Management, 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 effort. Applicants/offerors 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/offerors performing research outside of the United States will be determined at the time of application/proposal 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. 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 broad agency 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; and include the daily consultant fee, travel expenses, nature of the consulting effort; and why consultants are required for the proposed research project.

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 costs.

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/proposals involving an intragovernmental or intramural DOD organization, include a federal financial plan in the budget justification. The plan must address how any funds transferred to the intragovernmental or intramural DOD 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 DOD 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/proposals that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:

- The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location or population not generally available to investigators based in the 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.

(d) 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/Proposal Submission in eBRAP

Upon application/proposal submission, the organizational RM/Comptroller/Task Area Manager or equivalent Business Official will receive an email instructing them to log into eBRAP to review and approve the full application/proposal submission. eBRAP will validate full application/proposal files against the specific broad agency 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/offeror’s responsibility to review all application/proposal components and ensure proper ordering as specified in the broad agency announcement. Verification of application/proposal content is strongly recommended but not required. Modifications to application/proposal 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 Research & Related Budget Form cannot be changed after the application/proposal submission deadline.

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

The full application/proposal submission deadline and the end of the application/proposal verification period are stated in Section 1. Basic Information About the Funding Opportunity of the specific broad agency 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 USAMRDC 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/offeror 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/proposal recommended for funding are able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

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

- **Document Format:** Each attachment to the full application/proposal forms must be uploaded as an individual file in the format specified in the broad agency announcement. All contributors to the application/proposal must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application/proposal 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/proposal 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 Resolution:** 100 to 150 dots per inch

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

- **Language:** All documents must be submitted in English, unless otherwise specified in the broad agency 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/offerors to the CDMRP funding opportunities and other USAMRDC funding opportunities administered by the CDMRP to maintain the high integrity of its review processes. If an application/proposal is not recommended for funding and the applicant/offeror believes a factual or procedural error occurred during the review of the application/proposal, 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/offeror 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 broad agency announcement that describe peer and programmatic review (e.g., documents requested in the broad agency announcement and submitted with the original application/proposal 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/proposal review. 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 DOD OR U.S. DEPARTMENT OF VETERANS AFFAIRS RESOURCES

Access to certain DOD or U.S. Department of Veterans Affairs (VA) patient populations, resources, or databases may only be obtained by collaboration with a DOD or VA investigator who has a substantial role in the research and may not be available to a non-DOD or non-VA investigator if the resource is restricted to DOD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DOD or non-VA investigator collaborating with the DOD and/or VA. If access cannot be confirmed at the time of application/proposal 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).

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 DOD-provided infectious agents or toxins, select biological agents or toxins, specific chemical agent(s), or pesticides outside of an established laboratory. ***Applicants/offerors do not need to address these requirements in the initial application/proposal*** unless instructed otherwise in the broad agency announcement. PIs and organizational representatives will receive award-specific instructions if/when the application/proposal is recommended for funding.

Additional resources are available on the USAMRDC Safety and Environmental Resources page.

If applicants/offerors 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 USAMRDC Office of Human and Animal Research Oversight (OHARO) ensures that research conducted, contracted, sponsored, supported, or managed by the DOD and involving animals, human subjects, human data, human anatomical substances, and/or human cadavers is conducted in accordance with federal, DOD, Defense Health Agency (DHA), USAMRDC, and international regulatory requirements. PIs and applicant/offeror organizations **may not commence performance** of research involving any of the above until regulatory documents are submitted **and** approved by the respective USAMRDC OHARO office(s) to ensure that DOD regulations are met. All expectations described below are consistent with DoD Instruction (DoDI) 3216.01, 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/proposal submission, unless otherwise noted in the broad agency announcement. PIs and organizational representatives will receive award-specific instructions if/when the application/proposal is recommended for funding. Applicants/offerors are encouraged to review the Guide for Funded Investigators on the eBRAP Funding Opportunities and Forms page, and the other referenced websites below for additional information about post-award processes and requirements.

Additional information is available on the OHARO page.

Animal Care and Use Review Office

All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local IACUC of record, prior to using DOD funds to start work with animals. This includes reviewing and approving amendments to ongoing projects that will use DOD funds. When requested, PIs must submit the institutionally approved animal use protocol, documentation of IACUC approval of that protocol, and the completed ACURO Appendix. PIs should ***allow 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 USAMRDC 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 USAMRDC Headquarters for any country that is designated as Level 3 (Reconsider Travel) by the U.S. Department of State or DOD. 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/offeror 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/proposal selected for award proposing animal studies in a restricted country will be required to modify their request

during award negotiations. If an applicant/offeror 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 DOD-funded research involving new and ongoing research with human subjects, data, specimens, and/or cadavers must be reviewed and approved by the USAMRDC OHARO, Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) 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

Applicants/offerors should keep in mind the following key requirements as they plan any DOD-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 DOD institutions only).
- **Informed Consent Language:** The following must appear in the consent form:
    - A statement that the DOD is providing funding for the study.
    - A statement that representatives of the DOD are authorized to review research records.
    - In the event that Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom protected health information may be disclosed.
- **10 USC 980:** The requirements of 10 USC 980, Limitation on Use of Humans as Experimental Subjects, which are applicable to DOD-sponsored research, must be

considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless: (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent 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/offeror 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/offeror should plan for three to six months of additional time for the OHARO OHRO to review the submission and request Army Surgeon General or DOD approval of a waiver of the requirements of 10 USC 980.

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

Detailed guidance and instructions on OHRO review of DOD-funded research activities involving access, use, and analysis of human data and/or human anatomical substances is provided in the 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, DOD funds cannot be used to support or be used for the creation of a human embryo or embryos for research purposes (to include gene editing research); or for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than that allowed for research on fetuses in utero in accordance with 45 CFR 46.204(b), 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 human cadavers or human anatomical substances obtained from cadavers (postmortem samples) shall not begin until the USAMRDC OHARO grants approval in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training. The USAMRDC OHARO is the Action Office for this Army policy. **Additional requirements apply to use of cadaveric specimens obtained from outside of the United States and activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces.**

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

Disclosure of DOD-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 USAMRDC OHARO, USAMRDC Headquarters, and DOD Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical, and physical safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians and DOD contractors. DOD-funded research involving LSGD collected from DOD-

affiliated personnel may require that the performer obtain 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 DOD, as referenced in the approved SOW. If the DOD-funded activities have been added to an ongoing/existing protocol that is not DOD-funded, OHRO will require the PI to write a stand-alone protocol that is limited to those activities supported under the DOD award.

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

Single IRB Requirement: As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research must rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with 45 CFR 46.114(b), 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/proposal submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single POC for regulatory submissions and requirements.

Research Involving International Performance Sites: In addition to host nation and local requirements, U.S. research regulatory requirements apply when DOD-funded research is conducted outside the 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 USAMRDC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner to protect the confidentiality of subject information.

Research Involving 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 Applicable Clinical Trials to register on ClinicalTrials.gov. When entering study identification information, include the eBRAP log number as a Secondary ID for the study with the following designation: "CDMRP-eBRAP Log Number" (e.g., CDMRP-PC25####). 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.

As described in Section 801 of FDAAA, the Food and Drug Administration Amendments Act, and in 42 CFR Part 11, the Final Rule for Clinical Trials Registration and Results Information

Submission, studies that meet the definition of an Applicable Clinical Trial are required to submit study results information to ClinicalTrials.gov.

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

Posting of Informed Consent Forms: Studies that meet the definition of a **clinical trial** must post an IRB-approved informed consent form used to enroll subjects on a publicly available federal web site (e.g., ClinicalTrials.gov, Regulations.gov). The informed consent form must be posted on the federal web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any 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/proposal 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/offeror 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/offerors 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/proposal or abstract. Proprietary information should only be included in a full application/proposal if necessary for evaluation. Applicants/offerors should conspicuously and legibly mark any proprietary information that is included in the full application/proposal.

All applications/proposals 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/proposals 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/proposal and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns is disallowed and may result in application/proposal 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 USAMRDC shares application/proposal 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. Demographic and Career Information

To evaluate compliance with 20 USC 1681[a] et seq., Title IX of the Education Amendments of 1972, the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications/proposals in science, technology, engineering and/or mathematics (STEM) disciplines. The Research & Related Personal Data Form will be used by the DOD as the source of demographic information, such as sex, race, ethnicity, and disability information, for the PD/PI and all other persons identified as Co-PD(s)/Co-PI(s). The Research & Related Senior/Key Person Profile (Expanded) Form will be used by the DOD as the source for career information including Degree Type and Degree Year.

F. DOD Data Management Plan

If recommended for funding, a data management plan will be requested. DOD 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); and therefore applicants should not simply upload a copy of the NIH Data Management and Sharing Plan. The DOD Data Management Plan should be no more than two pages and submitted under "Supporting Documentation" only if a separate Data Management Attachment is ***not*** required by the funding opportunity. ***Do not duplicate the Data and Research Resources Sharing Plan.*** The DOD Data Management Plan 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."*)**.

G. 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.

H. Post-Award Organization and PI Changes

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

Transfer of Assistance Agreement: Unless restricted by the specific broad agency 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/proposal on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

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

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

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

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

J. 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 DOD. The requirement with specific language will be included in the award notice. Below is an example:

"This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs and the Defense Health Agency, Research & Engineering Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of (*insert total costs*), through the (*insert program name*) under Award No. (HT942525XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense."

(2) "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the ACURO website.

(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.

K. Property and Equipment

Assistance Agreements: Unless otherwise specified in the award, the title to equipment or other tangible property acquired with government funds will vest in institutions of higher education, 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 DOD reserves the right to require the transfer of equipment acquired with the award funds to the federal government or to an eligible third party.

Contracts: Reference FAR 45 and Defense Federal Acquisition Regulation Supplement (DFARS) 245.

L. 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 the eBRAP Funding Opportunities and Forms page. 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 DOD 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/offeror 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

APPENDIX 9
REPORTING REQUIREMENTS

If an application/proposal is recommended for funding, there are several types of reporting requirements 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/offeror organization, no new awards will be issued to the applicant/offeror organization until all delinquent reports have been submitted.

Details regarding Financial Reporting requirements are incorporated by reference into assistance agreements, with the Division III - USAMRAA Addendum to the DOD R&D General 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.

Service Contract Reporting (SCR): SCR is now a requirement for all DOD contracts. Offerors are allowed to include a nominal fee in their cost/price application/proposal for providing this data. A “nominal fee” is defined as a computation of an administrative assistant-equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. SCR costs/price will not be evaluated as part of the total evaluated application/proposal cost/price.

The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to report the information outlined in DFARS Clause 252.204-7023, for services performed during the preceding government fiscal year under the contract or order that exceed the threshold established in DFARS 204.1703.

Reporting input will be for the labor executed during the period of performance during each government fiscal year, which runs October 1 through September 30. While input may be reported any time during the fiscal year, all data shall be reported no later than October 31 of each calendar year.

APPENDIX 10
DEFINITION LIST

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

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

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

Animal Care and Use Review Office (ACURO): A component of the USAMRDC Office of Human and Animal Research Oversight (OHARO) 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/proposal 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 funding opportunity announcement (FOA) 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

35.016, 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.

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.

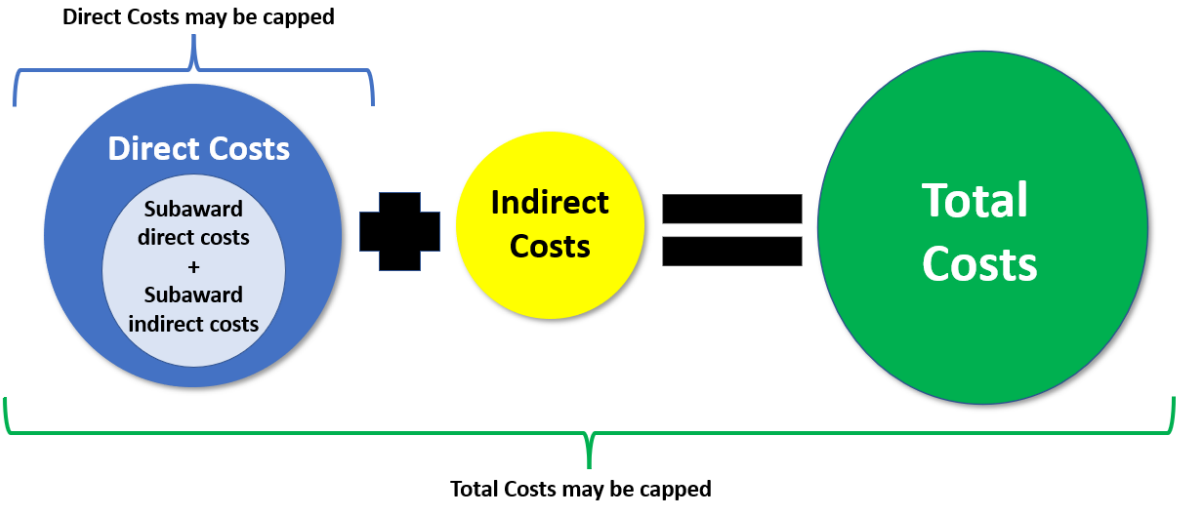
Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under 45 CFR 46.104(d)(4) of the Common Rule, Secondary Research for Which Consent is Not Required.

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. Costs may be capped by direct or total costs.



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.

Electronic Biomedical Research Application Portal (eBRAP): A secure web-based system that allows PIs and/or organizational representatives to submit pre-application/proposal materials, view and verify extramural full applications/proposals 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/proposals through eBRAP following pre-application/proposal submission.

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

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

Full Application: A completed application/proposal package including all required forms and attachments as described in the FOA. The CDMRP staff and contractors will review full application/proposal materials to ensure compliance with FOA 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.

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

General Submission Instructions (GSI): A document to be read in conjunction with the broad agency announcement that provides additional details and instructions for application/submission preparation and submission. The broad agency announcement provides the basic information necessary to prepare an application/proposal (i.e., what to submit); whereas the GSI provides additional details and instruction for both application/proposal 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: A federal system that must be used by funding agencies to announce extramural grant applications. Full applications/proposals for the CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application/proposal through eBRAP.

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/proposal 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/proposal submission. This term is specific for FOAs 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 DOD Organization: A subset of intragovernmental organizations; refers specifically to DOD organizations, including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

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

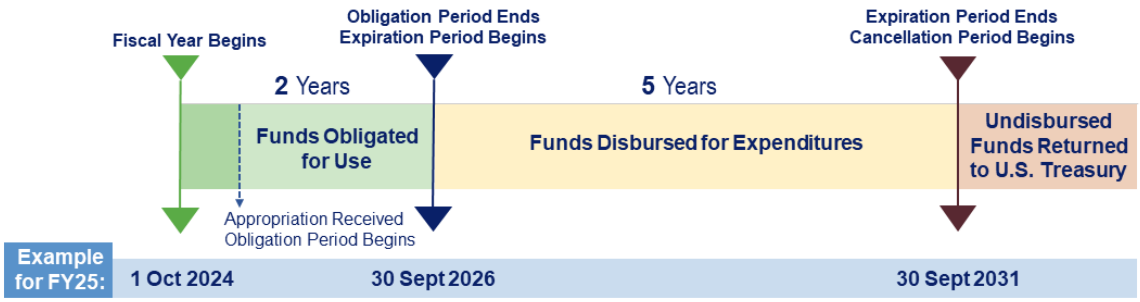
Knowledge Product: A non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, or tools or to support materiel solutions (systems to develop, acquire, provide, and sustain medical 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/proposal used for program planning purposes only. An invitation to submit a full application/proposal is NOT provided after LOI submission. Applicants/offerors are encouraged to develop the LOI and full application/proposal components concurrently and submit a full application/proposal AFTER successful submission of the ***required*** LOI. Full applications/proposals that are submitted without an LOI being submitted by the posted deadline will be rejected.

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.

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 and Animal Research Oversight (OHARO): The office within the USAMRDC that ensures CDMRP-funded research involving human subjects, human data and/or anatomical substances, or animals are conducted in accordance with federal, DOD, Army, USAMRDC and international regulatory requirements. The OHARO has three major subordinate offices: the ACURO; the Office of Human Research Oversight (OHRO); and the IRB Office.

Office of Human Research Oversight (OHRO): A component of the USAMRDC OHARO 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.

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 expected 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/proposals against established criteria outlined in each FOA to determine technical merit, where each application/proposal 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/proposal process, submitted through eBRAP. The CDMRP utilizes two types of pre-applications: Letter of Intent ***or*** Preproposal.

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

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

prepare an application/proposal 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/proposals with high scientific and technical merit are further evaluated for programmatic relevance according to criteria outlined in each FOA.

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/offeror to carry out a research project.

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

U.S. Army Medical Research Acquisition Activity (USAMRAA): The USAMRAA is the contracting and assistance agreement element of the USAMRDC. Items that fall under the purview of the USAMRAA 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.

APPENDIX 11
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
DFARS	Defense Federal Acquisition Regulation Supplement
CSI	Congressional Special Interest
DHA	Defense Health Agency
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
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
FOA	Funding Opportunity Announcement
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
NSF	U.S. National Science Foundation
NSPM-33	National Security Presidential Memorandum-33
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID
OT	Other Transaction (Award)
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
SCR	Service Contract Reporting
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
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs
WAV	Waveform Audio