

**General Application Instructions**

**Version 901**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

**Table of Contents**

**I. GENERAL INFORMATION ..... 2**

- A. How to Use the General Application Instructions (GAI) ..... 2
- B. Current Funding Opportunities and Email Notifications..... 2
- C. Agency Contacts ..... 3

**II. INTRODUCTION TO APPLICATION SUBMISSION ..... 3**

- A. Eligible Applicant Organizations..... 3
- B. Applications Involving Intragovernmental or Intramural DOD Organizations..... 3
- C. Pre-Application and Full Application Submission Portal Systems ..... 4
- D. Application Submission Overview ..... 4

**III. PRE-APPLICATION SUBMISSION..... 5**

- A. eBRAP Registration..... 5
- B. Content and Form of Pre-Application Submission..... 6

**IV. FULL APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS ... 8**

- A. Grants.gov Registration ..... 8
- B. Content and Form of Full-Application Submission - Grants.gov..... 10
- C. Submission to Grants.gov ..... 26
- D. Applicant Verification of Grants.gov Submission in eBRAP ..... 27

**V. FULL APPLICATION SUBMISSION FOR INTRAMURAL DOD ORGANIZATIONS ..... 27**

- A. Content and Form of Full Application Submission – eBRAP ..... 27
- B. Applicant Verification of Full Application Submission in eBRAP..... 40

**APPENDIX 1 Recipient Qualification and Restriction Information ..... 41**

**APPENDIX 2 Formatting Guidelines ..... 42**

**APPENDIX 3 Appeals and Inquiry Review Process ..... 44**

**APPENDIX 4 Use of DOD or Department of Veterans Affairs (VA) Resources..... 45**

**APPENDIX 5 Research BioSafety Requirements..... 46**

**APPENDIX 6 Research Protections Review Requirements ..... 47**

**APPENDIX 7 Administrative Information ..... 52**

**APPENDIX 8 National Policy Requirements..... 56**

**APPENDIX 9 Reporting Requirements..... 58**

**APPENDIX 10 Acronym List ..... 59**

## I. GENERAL INFORMATION

### A. How to Use the General Application Instructions (GAI)

The GAI is designed to be read in conjunction with the program announcement for a CDMRP funding opportunity. The program announcement provides basic information necessary to prepare an application (i.e., what to submit), whereas the GAI provides additional details and instruction for both application preparation and submission (i.e., how to submit). For accurate referencing, ensure that the version code on the cover page of the GAI matches the version code of the program announcement found in Section II.H.1, Program Announcement and General Application Instructions Versions.

The following symbols are used throughout the GAI:



Marks particularly helpful or important information.



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

### B. Current Funding Opportunities and Email Notifications

Funding opportunities currently offered through the U.S. Army Medical Research and Development Command (USAMRDC), including those issued by the Congressionally Directed Medical Research Program (CDMRP), may be viewed at <https://grants.gov>; users should enter Assistance Listing (AL) Number 12.420 when searching for CDMRP funding opportunities on Grants.gov. Applicants should subscribe on Grants.gov ([www.grants.gov/connect/manage-subscriptions](http://www.grants.gov/connect/manage-subscriptions)) to receive official notifications of new funding opportunity postings and updates. Applicants are encouraged to sign up to receive notifications of changes to specific funding opportunities through either (1) the “Send me change notification emails” link on the Synopsis page for the specific program announcement or (2) by responding to the prompt when first downloading the Grants.gov application package.

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

Information about funding opportunities may also be found on the CDMRP website at <https://cdmrp.health.mil/funding/>, and on the electronic Biomedical Research Application Portal (eBRAP) at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants who subscribe to program-specific news and updates under “Email Subscriptions” on eBRAP’s home page (<https://ebrap.org/eBRAP/programSubscription/Subscribe.htm>) will receive email notification of funding opportunity releases. Email notifications of funding opportunities from eBRAP are sent as a courtesy.

To facilitate that email correspondence is delivered correctly, and not treated as spam, Principal Investigators (PIs) and organizational representatives should keep email addresses up to date in both Grants.gov and eBRAP and place the following domains into any available email

“safelists”: health.mil, eBRAP.org, and Grants.gov. The same email addresses should be used when submitting both the pre-application and the full application.

### C. Agency Contacts

**eBRAP Help Desk:** Questions related to program announcement content or submission requirements, as well as questions related to submission of pre-applications or full applications from intramural organizations 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 (Monday through Friday, 8:00 a.m. to 5:00 p.m.)

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

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

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

Email: [support@grants.gov](mailto:support@grants.gov)

## II. INTRODUCTION TO APPLICATION SUBMISSION

### A. Eligible Applicant Organizations

Applications may be submitted by foreign or domestic 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 Involving Intragovernmental or Intramural DOD Organizations

It is strongly recommended that intragovernmental or intramural DOD investigators work closely with their respective Resource Manager (RM)/Task Area Manager/Comptroller or equivalent Business Official before application submission to determine (a) whether the organization can accept the current fiscal year of funds listed in the funding opportunity and (b) how they plan to obligate the current fiscal year funds by the expiration date. Applicants should assume that all project funding will be provided from the fiscal year listed in the funding opportunity and that

funds from future fiscal year(s) for any item (including travel) will not be provided. Additional budgetary information and considerations are included in this document for [non-DOD intragovernmental organizations](#), [extramural organizations collaborating with an intragovernmental or intramural DOD organization](#), and [intramural DOD organizations](#).

### C. Pre-Application and Full Application Submission Portal Systems

**eBRAP** <https://ebrap.org>, is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov, receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

eBRAP allows an organization's representatives and PIs to view and modify certain components of the full application submissions associated with them. It will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy and to ensure proper ordering as specified in the program announcement.

**Grants.gov** (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

### D. Application Submission Overview

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

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

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

***Extramural Submission:*** An application submitted by an extramural organization for an extramural or intramural investigator working within an intramural or extramural organization. (e.g., a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions). Full applications from extramural organizations *must* be submitted through Grants.gov Workspace (refer to [Section IV, Full Application Submission for Extramural Organizations](#)). Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn.

***Intramural Submission:*** An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. There is no preference from the funding organization which submission methodology is selected and submission through one or the other

portal does not place an application at any advantage during the review process. Intramural DOD organizations that are unable to submit to Grants.gov should submit through eBRAP (refer to [Section V, Full Application Submission for Intramural DOD Organizations](#)). For the remainder of this document it will be assumed that Intramural submissions will proceed through eBRAP.



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

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

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

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

### III. PRE-APPLICATION SUBMISSION

General information about eBRAP registration and pre-application submission is provided in this section. The eBRAP User Guide, found at <https://ebrap.org/eBRAP/public/UserGuide.pdf>, contains detailed instructions for these two processes.

#### A. eBRAP Registration

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



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

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 (Primary Organization Representative, AOR) to register the organization. The AOR does not need to complete the organization registration in eBRAP prior to the pre-application submission deadline

in order for the pre-application to be submitted. ***However, the organization’s eBRAP registration must be completed before the full application submission deadline to allow for processing, viewing, and modifying select components of the full application package during the application verification period.***

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

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

PIs are encouraged to utilize an Open Researcher and Contributor ID (ORCID) identifier and enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP. Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

## **B. Content and Form of Pre-Application Submission**



***For specific instructions regarding content of the pre-application submission components, refer to section II.D.2.a, Pre-Application Submission, in the program announcement for the funding opportunity.***



***All pre-application components must be submitted through eBRAP by the deadline specified on the first page of the program announcement.***

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

### **Incorrect selection of submission type will delay processing.**

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

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

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

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

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

**Tab 2 – Application Contacts:**

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

Select the performing organization (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 eBRAP drop-down list or invited in order for the pre-application to be submitted.

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

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



***No member of the Programmatic Panel may be named as a Collaborator or Key Personnel for the proposed research project, nor found to have assisted in the pre-application or application processes. Refer to the specific program announcement for a link to the list of Programmatic Panel members.***

**Tab 4 – Conflicts of Interest:** To avoid conflicts of interest during the screening and review processes, list all individuals, other than collaborators and key personnel, who may have a conflict of interest in the review of the application, including 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 program announcement. Pre-applications where the components exceed the specified page limits may be rejected, or excess pages deleted from the file. Refer to the specific



program announcement for detailed instructions. Documents should conform to the formatting guidelines outlined in [Appendix 2](#).

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

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



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

#### IV. FULL APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS

##### 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 8 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 <http://www.grants.gov/quick-start-guide/applicants>.

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

##### 1. Obtain Unique Entity Identifier (UEI) from System for Award Management (SAM)

The applicant organization must be registered as an Entity in SAM at <https://www.sam.gov/SAM/> and receive confirmation of an “Active” status before submitting an application through Grants.gov. *All federal awards including but not limited to contracts, grants, and cooperative agreements must use the UEI generated by SAM.gov.*

SAM validates organization information and electronically shares the secure and encrypted data with federal agencies’ finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an electronic business (E-Biz) POC, and a government business POC during the SAM registration process. *Entity registrations in SAM have an annual expiration. Verify the status of your organization’s Entity registration in SAM well in advance of the application submission deadline.* An organization can register in SAM online at <https://www.sam.gov/SAM/>. If your organization does not have either an Employer Identification Number (EIN) or Tax Identification



Number (TIN), allow at least 2 weeks to receive this information from the U.S. Internal Revenue Service. Allow several weeks to complete the entire SAM registration process.

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



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

## **2. Obtain Commercial and Government Entity (CAGE) Code**

The applicant organization must have a CAGE code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE codes. CAGE codes will be assigned to registrants as their SAM registration advances through the validation process. Foreign registrants in SAM must be assigned a North Atlantic Treaty Organization CAGE code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the organization is located or by visiting the website (<https://cage.dla.mil/Home/UsageAgree>). On average, CAGE code or NCAGE code validation in SAM occurs within 3 business days after the EIN or TIN is validated.

## **3. Register an AOR**

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

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



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

## **4. Create Grants.gov Workspace**

Applicants must create a Grants.gov Workspace, which allows the application components to be completed online and routed through the applicant organization for review prior to submission.

Once the Workspace has been created, participants (grant team members) can be added, and the required forms can be completed and reviewed before submitting. Specific information regarding the application process through Grants.gov Workspace can be found on the “Apply For Grants” page of Grants.gov ([www.grants.gov/applicants/grant-applications/how-to-apply-for-grants](http://www.grants.gov/applicants/grant-applications/how-to-apply-for-grants)).

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

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



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

## **B. Content and Form of Full-Application Submission - Grants.gov**

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

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

### **(a) SF424 (R&R), Application for Federal Assistance Form**

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

- **Block 1 – Type of Submission.** For original submissions, select the “Application” box. For changes that must be made after the original submission, the complete Grants.gov application package must be resubmitted with the “Changed/Corrected Application” box selected.
- **Block 2 – Date Submitted.** Enter the date the application is submitted.

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

- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.
- **Block 4a – Federal Identifier Box.** Enter the eBRAP log number assigned during pre-application submission.



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

- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/correct applications, enter the Grants.gov Tracking Number for the original application.
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. “Person to be contacted on matters involving this application” is the Business Official.
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue Service. If applying from an organization outside the United States, enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select “New” for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant’s Project.** Enter the same project title as used for the pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 00000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the application. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option b., “NO, program is not covered by E.O. 12372.”

- **Block 17 – Complete Certification.** Select the “I agree” box to provide the required certifications and assurances. By checking “I Agree” on the SF424 (R&R) block 17 you agree to abide by the following statement: *“By signing this application, I certify (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. (U.S. Code, Title 18, Section 1001).”*

By checking “I Agree” of the SF424 (R&R) block 17 you abide by the following statement: *‘By signing this application, I certify the proposing entity is in compliance with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 which requires that: (a) the PI and other key personnel certify that the current and pending support provided on the proposal is current, accurate, and complete; (B) agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the terms of the award; (c) the PI and other key personnel have been made aware of the requirements under Section 223(a)(1) of this Act.’*

Checking “I agree” confirms 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 Title 31 of United States Code, Section 1352 (31 USC 1352).
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant AOR organization’s authorized representative. The “Signature of Authorized Representative” is automatically completed upon submission of the Grants.gov application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.



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

#### (b) Attachments Form

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

Each attachment in the Attachments Form must be uploaded as an individual PDF 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 program announcement and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 megabytes (MB), and the file size for the entire Grants.gov application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center ([support@grants.gov](mailto:support@grants.gov)) for written confirmation that a file exceeding the maximum size will be accepted.



***Do not password protect any files of the application 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.***

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



***For specific instructions regarding additional attachments, attachment numbers, content, and page limits, refer to the program announcement. Attach each as a separate PDF, named as indicated in the announcement.***

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



***Submission of a Project Narrative that exceeds the page limit specified in the program announcement will result in administrative rejection of the application.***

**Attachment: Supporting Documentation: Combine and attach as a single PDF named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings.

Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed, or the application may be administratively withdrawn. ***Letters of support not requested in the program announcement, such as those from members of Congress, will be removed from the application package.***

**DOD Data Management Plan:** DOD Data Management Plans have specific basic requirements, as described in Section 3.c., Enclosure 3, and therefore applicants should not simply upload a copy of the National Institutes of Health (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 DOD Instruction 5230.09.”).***



***For a complete list and descriptions of required Supporting Documentation, refer to the program announcement.***

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

**Attachment: Lay Abstract: Attach as “LayAbs.pdf”.** Abstracts of all funded research projects will be posted on the CDMRP website at <https://cdmrp.health.mil>. ***Do not include proprietary or confidential information. Do not duplicate the technical abstract.*** Use only



characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

**Attachment: Statement of Work (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(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 are strongly encouraged to use the suggested SOW format stated in the program announcement. Templates for SOW formats are available on the eBRAP “Program Announcement & Forms” page at <https://ebrap.org/eBRAP/public/Program.htm>. The SOW must be in PDF format prior to attaching.

**Attachment: Suggested Intragovernmental/Intramural Budget Form, *if applicable*: Attach as “IGBudget.pdf”.**

When an intramural organization will be a collaborator in performance of an extramural award complete a separate “Suggested Intragovernmental/Intramural Budget Form” for each intramural organization involved in the project and upload as a single document. The “Suggested Intragovernmental/Intramural Budget Form” is available for download on the eBRAP “Funding Opportunities and Forms” page at <https://ebrap.org/eBRAP/public/Program.htm>. Detailed instructions for completing the “Suggested Intragovernmental/Intramural Budget Form” are provided in [Section V, Full Application Submission for Intramural DOD Organizations](#).

### **(c) Research & Related Personal Data**

Each application 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 who do not wish to provide information should check or select the “Do not wish to provide” option.

### **(d) Research & Related Senior/Key Person Profile (Expanded)**

Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project, including the provision of degree information. All fields marked with an asterisk are required. For the application PI, in the “PROFILE – Project Director/Principal Investigator” section, enter the PI’s User Name provided by eBRAP into the data field labeled “Credential, e.g., agency login” (Green Box, Figure 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 previous/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**

PROFILE - Project Director/Principal Investigator			
Prefix:	<input type="text"/>	* First Name:	<input type="text"/>
		Middle Name:	<input type="text"/>
* Last Name:	<input type="text"/>	Suffix:	<input type="text"/>
Position/Title:	<input type="text"/>		
Department:	<input type="text"/>		
Organization Name:	<input type="text"/>		
Division:	<input type="text"/>		
* Street1:	<input type="text"/>		
Street2:	<input type="text"/>		
* City:	<input type="text"/>	County/ Parish:	<input type="text"/>
* State:	<input type="text"/>	Province:	<input type="text"/>
* Country:	<input type="text"/>	* Zip / Postal Code:	<input type="text"/>
* Phone Number:	<input type="text"/>	Fax Number:	<input type="text"/>
* E-Mail:	<input type="text"/>		
Credential, e.g., agency login:	<input type="text" value="Enter PI's eBRAP User Name Here"/>		
* Project Role:	<input type="text"/>	Other Project Role Category:	<input type="text"/>
Degree Type:	<input type="text"/>		
Degree Year:	<input type="text"/>		
* Attach Biographical Sketch	<input type="text"/>	Add Attachment	Delete Attachment
Attach Current & Pending Support	<input type="text"/>	Add Attachment	Delete Attachment
		View Attachment	View Attachment

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

The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page at, <https://ebrap.org/eBRAP/public/Program.htm> in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format. Page limitations will be specified in the program announcement.

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

Provide support information for the PI and all senior/key personnel, including other individuals who will contribute to the scientific development or execution of the proposed research project in a substantive, meaningful way, independent of whether they request salaries or compensation. Compensation could take many forms including cash, research funding, complimentary foreign travel, honorific titles, career advancement opportunities, promised future compensation, or other types of remuneration or consideration, including in-kind compensation. Include the total or estimated dollar amount for research, resource, or other project support.

Consistent with National Security Presidential Memoranda-33, individuals are required to disclose grants and contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if individuals receive direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government sponsored or affiliated activity. ***“Foreign government-sponsored talent recruitment program” is defined as an effort organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position) as noted in the [Guidance for Implementing National Security for United States Government-Supported Research and Development](#), page 23.***

If there is no previous, current, or pending support, enter “None.” An updated previous, current, and pending support document will be required if an award is recommended for funding.

- **Research Support:** For all previous (award period of performance ending within the past 5 years), current, and pending (includes all proposals currently under review or pending award) research support, include the following:
  - Title of the project
  - Project number
  - Level of effort (percentage or calendar months)
  - Performance period (month/day/year – month/day/year)
  - Funding amount
  - Supporting agency
  - Supporting agency POC (name and contact information)
  - Specific aims/tasks
  - Brief description of the project’s goals
  - Description of any actual or potential overlap with the proposed research project. Clearly state if there is no overlap.
- **Positions and Appointments:** List all positions and scientific appointments, both domestic and foreign (including affiliations with foreign entities or governments), held by the PI and all senior/key personnel. This includes titled academic, professional, or

institutional appointments, independent of whether remuneration is received and/or whether the position/appointment is full time, part time, or voluntary (including adjunct, visiting, or honorary). Selection to a foreign “talents” or similar-type program must be reported.

- **Resources:** Report all other support including resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value. This includes but is not limited to foreign financial support, research or laboratory personnel, lab space, scientific materials such as high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.), or other foreign or domestic research support.
- **Other Projects and Activities:** Report all current projects and activities that involve the PI and all senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. Information must be provided for all current support for ongoing projects, whether such support is provided through the applicant organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel’s research efforts.

#### (e) 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 on the Grants.gov Research & Related Budget Form. For limits on funding amounts, types of costs, and period of performance, refer to the program announcement. *A budget justification **for the entire period of performance must be uploaded to [Section L](#) of the Research & Related Budget – Budget Period 1.*** The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. At the time of application submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate, and complete. The government reserves the right to request a revised budget and budget justification and/or additional information.



*If the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application 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, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” (2 CFR 200), as implemented by Chapter XI of Title 2 CFR
- Provisions of Chapter I, Subchapter C of Title 32, CFR, “DOD Grant and Agreement Regulations,” Parts 26, 28, 34.16, and Title 2, CFR Parts 1100-1199
- Federal Acquisition Regulation (FAR) Part 31



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

- **Cost of Preparing Applications:** The cost of preparing applications in response to a program announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications 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.
- **Timelines:** Programs are funded via Defense Health Program Research, Development, Test, and Evaluation (RDT&E) appropriations. RDT&E funds must be obligated or allocated 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 2024 [FY24] funds must be obligated no later than 30 September 2025). In addition to obligation deadlines, RDT&E funds will be available for use for a limited time period and expire for disbursement 5 years after the obligation deadline. Expired (i.e., undisbursed) funds return to the U.S. Treasury at the end of the 5-year disbursement period (e.g., FY24 funds expire for disbursement to performers by 30 September 2030.)
- **Funding to Intragovernmental and Intramural DOD Organizations:** The USAMRDC’s RM office will “direct fund” Intragovernmental/Intramural DOD Organizations utilizing either the Project Order Statute (41 USC 6307) or the Economy Act Statute (31 USC 1535), as appropriate. Where applicable, the Project Order Statute is the preferred transactional authority that will be used for intramural DOD organizations. Funds will be sent 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.

Intragovernmental and intramural DOD organizations must be prepared to accept the entirety of the requested budget for the site in the fiscal year funds indicated in the funding opportunity. Congressional Special Interest (CSI) appropriations for a given topic or program 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 through their agency’s procedures the use of contractual or assistance funding awards or other appropriate agreements to support any external collaborators. Intragovernmental and intramural DOD investigators and collaborators are reminded to

coordinate receipt and commitment of funds through their respective RM/Task Area Manager/Comptroller or equivalent Business Official.

- **Funding to 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 described in APAN 15-01. As noted above, funding to intragovernmental or intramural DOD organizations, including research collaborators, will be managed through a direct funds transfer from the USAMRDC's RM office.

Additionally, the intragovernmental or intramural DOD organization may require that a cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) be executed with the extramural recipient before work between the organizations can begin or funds can be provided to the intragovernmental organization. The CRADA (or other instrument) is not required at the time of application submission. A timeline for execution of the agreement should be included within the project's SOW.

- **Pre-Award Costs:** If an application is recommended for funding, an institution of higher education, hospital, or 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.

The incurrence of pre-award costs in anticipation of an award imposes no obligation on the government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred or in the absence of appropriations. The government expects the 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 proposed research objectives within the approved timeframe or in any way adversely affect the conduct of the project.

**Budget Instructions:** Complete 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 Project Narrative and SOW.



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

## Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the Research & Related Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).
- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. *For most federal agencies, funding cannot be applied toward federal salaries 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 is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed.

## 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 is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

**Section C: Equipment Description.** Equipment is tangible personal property (including information technology systems) having a useful life of more than 1 year and a per unit acquisition cost that equals or exceeds the lesser of (a) \$5,000 or (b) the recipient’s or the subrecipient’s capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project.

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

*Funds to an extramural organization may not be used to cover travel costs for 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” means 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. (see [Research & Related Subaward Budget Attachment\(s\)](#))



***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 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 program 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), 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 DHHS (<https://www.hhs.gov/about/agencies/asa/psc/indirect-cost-negotiations/index.html>), the Office of Naval Research (<https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award>), and the Defense Contract Audit Agency (<https://www.dcaa.mil/>) for additional information on indirect rates.

**Section I: Total Direct and Indirect Costs.** State the total costs (i.e., summation of 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 to Section L of the Research & Related Budget – Budget Period 1. 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 performing research outside of the United States should also include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for applicants performing research outside of the United States will be determined at the time of application submission.

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

**Equipment:** If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (a) Special test equipment to be fabricated for specific research purposes and its cost. (b) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately. (c) 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 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 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:** CDMRP funding is directed by Congress on a yearly basis for each program and obligated up-front for each award as there is no guarantee of future program appropriations. Funds are available for obligation for 2 years from the beginning of the fiscal year of appropriation. For applications involving an intragovernmental organization, include a federal financial plan in the budget justification. The plan must address how all 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. *Unless otherwise stated in the funding opportunity, CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.*

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

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

**(f) 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.

**(g) Research & Related Subaward Budget Attachment(s) Form (if applicable)**

**Extramural Subaward(s):** Complete a separate Research & Related Budget, 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:** Complete a separate “Suggested Intragovernmental/Intramural Budget Form”, including a budget justification, for each intramural subaward using the instructions in [Section V, Full Application Submission for Intramural DOD Organizations](#) and upload as a single document titled **IGBudget.pdf** to the Grants.gov Attachment 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 program announcement.*

**C. Submission to Grants.gov**



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

All applications must be received by the deadline indicated on the first page of the respective program announcement (Section I, Overview of the Funding Opportunity). Proof of timely submission is automatically recorded by Grants.gov. An electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The applicant

AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the application. Applicant AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the application's timely submission. The submission of a Workspace package can be tracked from the Workspace or by visiting Grants.gov (<https://grants.gov/applicants/grant-applications/track-my-application>) and entering the Tracking Number.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

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



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

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



***The full application submission deadline and the end of the application verification period are stated on the first page of the specific program announcement (Section I, Overview of the Funding Opportunity).***

### **V. FULL APPLICATION SUBMISSION FOR INTRAMURAL DOD ORGANIZATIONS**

#### **A. Content and Form of Full Application Submission – eBRAP**

##### **(a) eBRAP Full Application Package Components**

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

**Tab 1 – Summary:** Provides a summary of the application information and copies of standard application forms.

**Tab 2 – Contacts:** This tab will be populated by eBRAP. Add the name of the AOR.

**Tab 3 – Full Application Files:** Upload each application component in eBRAP as individual PDF files. Refer to [Appendix 2](#) for detailed formatting guidelines.

**Tab 4 – Application and Budget Data:** Review and edit Proposed Project Start Date, Proposed End Date, and budget data pre-populated from the Budget Form.

**Tab 5 – Submit/Request Approval Full Application:** Once all components have been uploaded, and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will validate files against the program announcement requirements, and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. eBRAP will notify your RM/Comptroller/Task Area Manager or equivalent Business Official by email to log into eBRAP to review and approve the full application package prior to the approval deadline.

## (b) Attachments

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

**Upload attachments to Tab 3 – Full Application Files.** Each attachment must be uploaded as an individual PDF unless otherwise stated. Do not password protect any files of the application 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.***

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



***For specific instructions regarding additional attachments, attachment numbers, content, and page limits, refer to the program announcement. Attach each as a separate PDF, named as indicated in the announcement.***

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



***Submission of a Project Narrative that exceeds the page limit specified in the program announcement will result in administrative rejection of the application.***

**Attachment: Supporting Documentation: Combine and attach as a single PDF named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation



attachment should not include information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings.

Submitting material that is not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed, or the application may be administratively withdrawn. ***Letters of support not requested in the program announcement, such as those from members of Congress, will be removed from the application package.***

**DOD Data Management Plan:** DOD Data Management Plans have specific basic requirements as described in Section 3.c., Enclosure 3, [DoD Instructions 3200.12](#) 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 DOD Instruction 5230.09.”).***



***For a complete list and descriptions of required Supporting Documentation, refer to the program announcement.***



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

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

**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 program announcement. Templates for SOW formats are available on the eBRAP “Program Announcement & Forms” page at <https://ebrap.org/eBRAP/public/Program.htm>. The SOW must be in PDF format prior to attaching.

### **(c) Research & Related Personal Data**

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

### **(d) Research & Related Senior/Key Person Profile (Expanded)**

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

**Figure 2. PI's eBRAP User Name**

PROFILE - Project Director/Principal Investigator			
Prefix:	<input type="text"/>	* First Name:	<input type="text"/>
		Middle Name:	<input type="text"/>
* Last Name:	<input type="text"/>	Suffix:	<input type="text"/>
Position/Title:	<input type="text"/>		
Department:	<input type="text"/>		
Organization Name:	<input type="text"/>		
Division:	<input type="text"/>		
* Street 1:	<input type="text"/>		
Street 2:	<input type="text"/>		
* City:	<input type="text"/>	County/ Parish:	<input type="text"/>
* State:	<input type="text"/>	Province:	<input type="text"/>
* Country:	<input type="text"/>	* Zip / Postal Code:	<input type="text"/>
* Phone Number:	<input type="text"/>	Fax Number:	<input type="text"/>
* E-Mail:	<input type="text"/>		
Credential, e.g., agency login:	<input type="text" value="Enter PI's eBRAP User Name Here"/>		
* Project Role:	<input type="text"/>	Other Project Role Category:	<input type="text"/>
Degree Type:	<input type="text"/>		
Degree Year:	<input type="text"/>		
* Attach Biographical Sketch	<input type="text"/>	Add Attachment	Delete Attachment
Attach Current & Pending Support	<input type="text"/>	Add Attachment	Delete Attachment
		View Attachment	View Attachment

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.

The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page at, <https://ebrap.org/eBRAP/public/Program.htm> in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format. Page limitations will be specified in the program announcement.

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

Provide support information for the PI and all senior/key personnel, including other individuals who will contribute to the scientific development or execution of the proposed research project in a substantive, meaningful way, independent of whether they request salaries or compensation. Compensation could take many forms including cash, research funding, complimentary foreign travel, honorific titles, career advancement

opportunities, promised future compensation, or other types of remuneration or consideration, including in-kind compensation. Include the total or estimated dollar amount for research, resource, or other project support.

Consistent with National Security Presidential Memoranda-33, individuals are required to disclose grants and contracts associated with participation in programs sponsored by foreign governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs. Further, if individuals receive direct or indirect support that is funded by a foreign government-sponsored talent recruitment program, even where the support is provided through an intermediary and does not require membership in the foreign government-sponsored talent recruitment program, that support must be disclosed. Individuals must also report other foreign government sponsored or affiliated activity. ***Foreign government-sponsored talent recruitment program” is defined as an effort organized, managed, or funded by a foreign government, or a foreign government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position) as noted in the [Guidance for Implementing National Security for United States Government-Supported Research and Development](#), page 23.***

If there is no previous, current, or pending support, enter “None.” An updated previous, current, and pending support document will be required if an award is recommended for funding.

**Research Support:** For all previous (award period of performance ending within the past 5 years), current, and pending (includes all proposals currently under review or pending award) research support, include the following:

- Title of the project
- Project number
- Level of effort (percentage or calendar months)
- Performance period (month/day/year – month/day/year)
- Funding amount
- Supporting agency
- Supporting agency POC (name and contact information)
- Specific aims/tasks
- Brief description of the project’s goals
- Description of any actual or potential overlap with the proposed research project.  
***Clearly state if there is no overlap.***

**Positions and Appointments:** List all positions and scientific appointments, both domestic and foreign (including affiliations with foreign entities or governments), held by the PI and all senior/key personnel. This includes titled academic, professional, or institutional appointments, independent of whether remuneration is received and/or whether the position/appointment is full time, part time, or voluntary (including adjunct, visiting, or honorary). Selection to a foreign “talents” or similar-type program must be reported.

**Resources:** Report all other support including resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of monetary value. This includes but is not limited to foreign financial support, research or laboratory personnel, lab space, scientific materials such as high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.), or other foreign or domestic research support.

**Other Projects and Activities:** Report all current projects and activities that involve the PI and all senior/key personnel, even if the support received is only in-kind (e.g., office/laboratory space, equipment, supplies, employees). This includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers supported by other sources of funding. Information must be provided for all current support for ongoing projects, whether such support is provided through the applicant organization, through another domestic or foreign organization, or is directly provided to an individual who supports the senior/key personnel’s research efforts.

#### (e) 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” web page at, <https://eBRAP.org>. For limits on funding amounts, types of costs, and period of performance, refer to the program announcement. ***A budget justification for the entire period of performance that includes a Federal Financial Plan must be appended to the “Suggested Intragovernmental/Intramural Budget Form”.*** The budget and budget justification should include sufficient detail for the government to determine whether the proposed costs are allowable, allocable, and reasonable for the proposed research. The government reserves the right to request a revised budget and budget justification and/or additional information.



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

## Budget Regulations and Restrictions:

- **Administrative and Cost Principles:** Recipients will be required to comply with the following, as applicable:
  - “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” (2 CFR 200), as implemented by Chapter XI of Title 2 CFR
  - Provisions of Chapter I, Subchapter C of Title 32, CFR, “DOD Grant and Agreement Regulations,” Parts 26, 28, 34.16, and Title 2, CFR Parts 1100-1199.
  - FAR Part 31



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

- **Cost of Preparing Applications:** The cost of preparing applications in response to a program announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications 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.
- **Timelines:** Programs are funded via Defense Health Program RDT&E appropriations. RDT&E funds must be obligated or allocated to a specific award or purpose within 24 months from the start of the fiscal year in which the funds were appropriated (e.g., FY24 funds must be obligated no later than 30 September 2025). In addition to obligation deadlines, RDT&E funds will be available for use for a limited time period and expire for disbursement 5 years after the obligation deadline. Expired (i.e., undisbursed) funds return to the U.S. Treasury at the end of the 5-year disbursement period (e.g., FY24 funds expire for disbursement to performers by 30 September 2030).
- **Funding:** The USAMRDC’s RM office will “direct fund” Intragovernmental/Intramural Organizations utilizing either the Project Order Statute (41 USC 6307) or the Economy Act Statute (31 USC 1535), as appropriate. Where applicable, the Project Order Statute is the preferred transactional authority that will be used for intramural DOD organizations. Funds will be sent by the authorized method through the MIPR, FAD, or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals.

Intragovernmental and intramural DOD organizations must be prepared to accept the entirety of the requested budget for the site in the fiscal year funds aligned with the funding opportunity. CSI appropriations for a given topic or program are not part of the requested DOD budget and are not guaranteed in the future. Intragovernmental and intramural DOD investigators are responsible for coordinating through their agency’s procedures the use of contractual or assistance funding awards or other appropriate agreements to support any external collaborators. Intragovernmental and intramural

DOD investigators and collaborators are reminded to coordinate receipt and commitment of funds through their respective RM/Task Area Manager/Comptroller or equivalent Business Official.

- **CRADA:** If an extramural collaborator will be involved in the performance of the proposed research, it may be necessary for a CRADA or other instrument (as authorized by law or regulation) to be executed with the collaborator before work between the organizations can begin. The CRADA (or other instrument) is not required at the time of application submission. A timeline for execution of the agreement should be included within the project's SOW.
- **Pre-Award Costs:** An institution of higher education, hospital, other nonprofit, or for-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award if such costs (1) are necessary to conduct the project and (2) would be allowable under the award, if awarded. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer's approval before incurring the cost. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new award.

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

#### **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 1 year and a per unit acquisition cost that equals or exceeds the lesser of (a) \$5,000 or (b) the recipient's or the subrecipient's capitalization threshold for financial statement purposes. Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project.
- **Materials and Supplies:** "Materials and Supplies" means all tangible property, including a computing device, acquired under an award that does not meet the definition of equipment.
- **Military and Federal Civilian Travel Costs:** Applicants are responsible for budgeting all costs associated with travel, including airfare, hotel, etc., 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 program announcement.***

- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the Justification section. The government reserves the right to disallow any indirect costs not sufficiently justified. No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate.
- **Total Direct and Indirect Costs:** This section is calculated automatically from the data provided.
- **Required Information (last page of the form):**
  - Indicate the name and contact information for the 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 6 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 performing research outside of the United States should also include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for applicants performing research outside of the United States will be determined at the time of application submission.

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

**Equipment:** If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (a) Special test equipment to be fabricated for specific research purposes and its cost. (b) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately. (c) 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 program announcement.

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

**Consultant Services:** Independent of whether funds are requested for any proposed consultant services, include the name(s) and organizational affiliation(s) of all consultants, 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:** CDMRP funding is directed by Congress on a yearly basis for each program and obligated up-front for each award as there is no guarantee of future program appropriations. Funds are available for obligation for 2 years from the beginning of the fiscal year of appropriation. For applications involving an intragovernmental or intramural DOD organization, include a federal financial plan in the budget justification. The plan must address how all 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. *Unless otherwise stated in the funding opportunity, CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.*

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

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

#### **(f) 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.

## **B. Applicant Verification of Full Application Submission in eBRAP**

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



***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.***

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



***The full application submission deadline and the end of the application verification period are stated on the first page of the specific program announcement (Section I, Overview of the Funding Opportunity).***

## **APPENDIX 1**

### **RECIPIENT QUALIFICATION AND RESTRICTION INFORMATION**

#### **A. Recipient Qualification**

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

The federal government will not provide funds to support scientists from countries meeting the criteria for designation as a State Sponsor of Terrorism (<https://www.state.gov/j/ct/list/c14151.htm>).

The USAMRDC utilizes the Exclusions Within the Performance Information functional area of SAM to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at <https://www.sam.gov/SAM/>. 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, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

#### **B. J-1 Visa Waiver**

Each organization, including organizations located outside of the United States, is responsible for ensuring that the personnel associated with any application recommended for funding are able to complete the work without intercession by the 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 following Department of State website: <https://travel.state.gov/content/travel/en/us-visas.html>.

#### **C. Post-Employment Restrictions**

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

## APPENDIX 2 FORMATTING GUIDELINES

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

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

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



### APPENDIX 3 APPEALS AND INQUIRY REVIEW PROCESS

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

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

- **Factual Error:** An error in the review (peer or programmatic) that is restricted to, or based on, fact. Differences of opinion between reviewers or between reviewer(s) and an applicant are not factual errors.
- **Procedural Error:** An error in the review (peer or programmatic) that is restricted to review process adherence. The review process did not follow the procedures in the program announcement that describe peer and programmatic review (e.g., documents requested in the program announcement and submitted with the original application were inadvertently left out of the peer or programmatic review package).

The purpose of the IRP is to assess whether an error occurred during application review. 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](mailto:help@eBRAP.org).

## **APPENDIX 4**

### **USE OF DOD OR DEPARTMENT OF VETERANS AFFAIRS (VA) RESOURCES**

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

**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 use of Army-provided infectious agents or toxins, Biological Select Agents or Toxins (<https://www.selectagents.gov/sat/list.htm>), specific chemical agent(s) ([https://www.cwc.gov/cwc\\_treaty\\_chemicals\\_schedules.html](https://www.cwc.gov/cwc_treaty_chemicals_schedules.html)), or pesticides outside of an established laboratory. *Applicants do not need to address these requirements in the initial application* unless instructed otherwise in the program announcement. PIs and organizational representatives will receive award-specific instructions if/when the application is recommended for funding.

Additional information is available at  
[https://mrhc.health.mil/index.cfm/resources/researcher\\_resources/safety](https://mrhc.health.mil/index.cfm/resources/researcher_resources/safety)

If applicants have questions, they may call 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 [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules – Office of Science Policy \(nih.gov\)](#).

**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 United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern with appropriate reporting and oversight.

More information on DURC policy and oversight can be found at  
<https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab0/>.

## 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, Army, USAMRDC, and international regulatory requirements. PIs and applicant organizations **may not commence performance** of research involving any of the above until regulatory documents are submitted **and** approved by the respective USAMRDC OHARO office(s) to ensure that DOD regulations are met. All expectations described below are consistent with DODI 3216.01, “Use of Animals in DoD Programs,” and DODI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research.”

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

For additional information about OHARO visit,  
[https://mrdc.health.mil/index.cfm/collaborate/research\\_protections](https://mrdc.health.mil/index.cfm/collaborate/research_protections).

### **Animal Care and Use Review Office (ACURO)**

All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO ACURO, in addition to the local IACUC of record, prior to using DOD funds to start work with animals. This includes reviewing and approving amendments to ongoing projects that will use DOD funds. When requested, PIs must submit the institutionally approved animal use protocol, documentation of IACUC approval of that protocol, and the completed ACURO Appendix. PIs should ***allow 3 to 4 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 USAMRDC as a part of their responsibility to protect animals in research.

For current information about ACURO policies, detailed guidance, and the ACURO Appendix, visit [https://mrdc.health.mil/index.cfm/collaborate/research\\_protections/acuro](https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro). ***Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.***

Send questions via email to the ACURO ([usarmy.detrick.medcom-usamrdc.other.acuro@health.mil](mailto: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 review. PIs should ***allow up to 3 months to complete the OHRO regulatory review and approval process following submission of all required and complete documents to the OHRO.*** Studies taking place in international settings may require additional time for completion of OHRO reviews.

For current information about OHRO policies, detailed guidance, and submission forms, visit [https://mrdc.health.mil/index.cfm/collaborate/research\\_protections/hrpo](https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo).

Questions regarding applicable research protection regulations, policies, and guidance should be directed to the local IRB or the OHRO ([usarmy.detrick.medcom-usarmmc.other.hrpo@health.mil](mailto:usarmy.detrick.medcom-usarmmc.other.hrpo@health.mil)).

### **A. Human Subjects Research**

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

- **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current DHHS Office for Human Research Protection Federalwide Assurance (FWA) or DOD Assurance (Intramural DOD institutions only).
- **Informed Consent Language:** The following must appear in the consent form:
  - A statement that the DOD is providing funding for the study.
  - A statement that representatives of the DOD are authorized to review research records.
  - In the event that Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DOD must be listed as one of the parties to whom private health information may be disclosed.
- **10 USC 980 Waiver:** If the applicant proposes to conduct a trauma clinical trial or other planned emergency research under the 21 CFR 50.24 provisions for exception from informed consent, the applicant should plan for 3-6 months of additional time for the OHARO OHRO to review the submission and request Army Surgeon General or DOD approval of a waiver of the requirements of 10 USC 980, a DOD-unique statute involving use of DOD funds.

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

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

Detailed guidance and instructions on OHRO review of DOD-funded research activities involving access, use, and analysis of human data and/or human anatomical substances is provided in the “Information for Investigators – Research with Data/Specimens” guidance document on the OHRO website. This guidance document also includes a detailed discussion on the types of human data, cell lines, specimens, etc., that do and 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;
- and the source of the materials is documented (institution, clinical providers, nonprofit repositories, etc.)

Additional approvals are required for research with fetal tissues in accordance with DOD Instruction 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.

#### **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 ([https://mrdc.health.mil/assets/docs/orp/Army\\_Policy\\_for\\_Use\\_of\\_Human\\_Cadavers.pdf](https://mrdc.health.mil/assets/docs/orp/Army_Policy_for_Use_of_Human_Cadavers.pdf)). The USAMRDC OHARO is the Action Office for this Army policy. **Additional requirements apply to use of cadaveric specimens obtained from outside the U.S. and activities involving exposure of cadavers to impacts, blasts, ballistics testing, crash testing, and other destructive forces.**

#### **E. Large-Scale Genomic Data (LSGD) Collected from DOD-Affiliated Personnel**

Disclosure of DOD-affiliated personnel's LSGD may pose a national security risk; accordingly, such research (including the secondary use or sharing of identified or de-identified data or specimens) requires inclusion of administrative, technical, and physical safeguards commensurate with risk. The study must undergo security review and additional approvals by the USAMRDC OHARO, USAMRDC Headquarters, and DOD Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical, and physical safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors. DOD-funded research involving LSGD collected from DOD-affiliated personnel may require that the performer obtain a NIH Certificate of Confidentiality (<https://grants.nih.gov/policy/humansubjects/coc.htm>). 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). ***This includes certain types of work with human data and/or human specimens if that work has not been/will not be deemed exempt.*** If the proposed, non-exempt research involves more than one U.S.-based institution, a written plan for single IRB review arrangements must be provided at the time of



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

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

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

**Clinical Trial Registry:** PIs are required to register applicable clinical trials individually on <https://clinicaltrials.gov/> using a Secondary Protocol ID number designation of “CDMRP-eBRAP Log Number” (e.g., CDMRP-PC22#####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “CDMRP-eBRAP Log Number-A, -B, -C, etc.” (e.g., CDMRP-PC22#####-A). Clinical trials must be registered prior to enrollment of the first subject. All trials that meet the definition on the NIH database (see <https://prsinfo.clinicaltrials.gov/>, click on “Support Materials [including data element definitions]”) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85. PIs conducting phase 3 clinical trials shall submit results of analyses of group differences on the basis of sex/gender, race, and/or ethnicity to [clinicaltrials.gov](https://clinicaltrials.gov/) at the time of final report submission. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

## **APPENDIX 7 ADMINISTRATIVE INFORMATION**

### **A. Disclosure and Marking of Proprietary Information**

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

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

### **B. Classified Information, Data, or Outcomes**

In accordance with 32 CFR, Section 2002.4, inclusion of classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns is disallowed and may result in application withdrawal. Classified is defined as information that has been determined pursuant to Executive Order 13526 to require protection against unauthorized disclosure and is marked to indicate its classified status when in documentary form (to include electronic copies).

### **C. Sharing of Application Information**

The USAMRDC shares application information with other federal funding agencies (e.g., NIH, National Science Foundation, VA) to inform funding priorities and decisions, and to increase transparency. In addition, award data are made available to the public through the CDMRP website and to other organizations such as the International Cancer Research Partnership. By sharing and leveraging this information, coordination is enhanced and duplication of effort can be avoided, maximizing the impact of federal funds. The CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health. Updates on CDMRP-funded awards including awardee information and published results are shared on the Defense Technical Information Center (DTIC).

### **D. Demographic and Career Information**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), 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 in science, technology, engineering, and/or mathematics (STEM) disciplines. The Research & Related Personal Data form will be used by DOD as the source of demographic information, such as gender, 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.

## **E. 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.

## **F. Post-Award Organization and PI Changes**

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

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

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

## **G. FOIA Requests**

The FOIA (5 USC 552) 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 Act (<https://www.justice.gov/oip>).

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

## **H. Information Release**

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. "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 J9, Research and Development Directorate, or the U.S. Army Medical Research Acquisition Activity at the U.S. Army Medical Research and Development Command, in the amount of (*insert total costs*), through the (*insert program name*) under Award No. (HT9425241XXXX). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”

- (2) “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the ACURO website. ([https://mrhc.health.mil/index.cfm/collaborate/research\\_protections/acuro](https://mrhc.health.mil/index.cfm/collaborate/research_protections/acuro)).
- (3) “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<https://www.nih.gov/>)
- (4) “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” ([https://www.cdc.gov/safelabs/resources-tools/biosafety-resources-and-tools.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsafelabs%2Fresources-tools.html](https://www.cdc.gov/safelabs/resources-tools/biosafety-resources-and-tools.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fsafelabs%2Fresources-tools.html))

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

## **I. Contracted Fundamental Research**

Any awards to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DOD definition of “Contracted Fundamental Research.” The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

## **J. Property/Equipment**

Unless otherwise specified in the award, the title to equipment or other tangible property acquired with government funds will vest in institutions of higher education, nonprofit, and for-

profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the government. However, if the award is subsequently transferred to a new organization, the 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.

#### **K. Title to Inventions and Patents**

In accordance with the Bayh-Dole Act (35 USC 200 et seq.), 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.

## 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 and is a prerequisite for making or entering into an award over \$100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (R&R) (Application for Federal Assistance) 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 form for completion and submission is posted in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). 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), represents:

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

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

### **C. National Policy Requirements**

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

- Nondiscrimination
- Environmental Standards
- Live Organisms (Human Subjects and Animals)
- Debarment and Suspension
- Drug-Free Workplace
- Lobbying
- Officials Not to Benefit
- Hatch Act
- Native American Graves Protection and Repatriation Act
- Fly America Act
- Use of United States Flag Vessels
- Research Misconduct
- Requirements for an Institution of Higher Education Concerning Military Recruiters and Reserve Officer Training Corps
- Historic Preservation
- Relocation and Real Property Acquisition
- Confidentiality of Patient Records
- Pro-Children Act
- Constitution Day
- Trafficking in Persons
- Whistleblower Protections
- Certain Internal Confidentiality Agreements
- FY21 National Defense Authorization Act, Section 223(a), (a1) 18 USC 1001
- FY24 National Defense Authorization Act, Sections 1223 and 1224



## APPENDIX 9 REPORTING REQUIREMENTS

If an application 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 can be found on the USAMRDC Technical Reporting Requirements website at [https://mrdc.health.mil/index.cfm/resources/researcher\\_resources/reporting/technical](https://mrdc.health.mil/index.cfm/resources/researcher_resources/reporting/technical).

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

Details regarding Financial Reporting requirements are incorporated by reference into assistance agreements, with the Division III - USAMRAA Addendum to the DOD R&D General Terms and Conditions, available at <https://usamraa.health.mil/Pages/Resources.aspx>. More general financial information is also incorporated by reference into assistance agreements and can be found in the DOD Research and Development General Terms and Conditions at <https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions>. Organizational representatives and PIs should be sure to refer to the terms and conditions that are specific to the fiscal year in which their assistance agreement is issued.

## APPENDIX 10 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
CAGE	Commercial and Government Entity
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CRADA	Cooperative Research and Development Agreement
CSI	Congressional Special Interest
DHHS	Department of Health and Human Services
DOD	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
FOIA	Freedom of Information Act
FWA	Federalwide Assurance
FY	Fiscal Year
G&A	General and Administrative
GAI	General Application Instructions
GSA	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
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
PD	Project Director
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
R&R	Research & Related
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
RPPR	Research Performance Progress Report
SAM	System for Award Management
SCO	Senior Contracting Official
SF	Standard Form
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