

General Submission Instructions

**Broad Agency Announcement for Extramural Research (Program Specific) for the
Department of Defense**

Defense Health Program

Congressionally Directed Medical Research Programs

Combat Readiness – Medical Research Program (CRRP)

Translational Research Award (TRA)

Funding Opportunity Number: HT9425S24CRRPTRA

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I. GENERAL INFORMATION

A. How to Use the General Submission Instructions (GSI)

The GSI is designed to be read in conjunction with the Broad Agency Announcement for the CRRP Translational Research Award.

The following symbols are used throughout the GSI:



Marks particularly helpful or important information.



Refers the reader to the Broad Agency Announcement for specific instructions or additional information.

B. Current Funding Opportunities and Email Notifications

Funding opportunities currently offered through the U.S. Army Medical Research and Development Command (USAMRDC), including those issued by the 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/offerors should subscribe on Grants.gov (www.grants.gov/connect/manage-subscriptions) to receive official notifications of new funding opportunity postings and updates. Applicants/offerors are encouraged to sign up to receive notifications of changes to specific funding opportunities through either (1) the “Send me change notification emails” link on the Synopsis page for the specific Broad Agency Announcement, or (2) by responding to the prompt when first downloading the Grants.gov application/proposal package.

It is incumbent upon the applicant/offeror to check for published updates to the funding opportunity and the application/proposal package prior to submission; the applicant/offeror is responsible for using the latest version of the full application/proposal package. If the Grants.gov application/proposal package is updated or changed, previous versions of the application/proposal 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/offerors 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/proposal and the full application/proposal.

C. Agency Contacts

eBRAP Help Desk: Questions related to Broad Agency Announcement content or submission requirements, as well as questions related to submission of pre-applications/proposals 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

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

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

Email: support@grants.gov

II. INTRODUCTION TO APPLICATION/PROPOSAL SUBMISSION

A. Eligible Applicant/Offeror Organizations

Applications/proposals may be submitted by foreign or domestic extramural 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.

B. Applications/Proposals Involving Intragovernmental or Intramural DOD Organizations

Applications/proposals from an intramural DOD organization or from an extramural intragovernmental organization may be submitted to Grants.gov through a research foundation. ***It is also permissible, however, for an intramural DOD investigator to be named as a collaborator on an application submitted through an extramural organization.*** 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/offerors 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](#), and [extramural organizations collaborating with an intragovernmental or intramural DOD organization](#).

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

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

eBRAP allows an organization's representatives and PIs to view and modify certain components of the full application/proposal submissions associated with them. It will validate full application/proposal files against the specific Broad Agency 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/offeree's responsibility to review all application components for accuracy and to ensure proper ordering as specified in the Broad Agency Announcement.

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

D. Application/Proposal Submission Overview

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

STEP 1. Pre-application/proposal submission: All pre-applications/proposals *must* be submitted through eBRAP.

STEP 2. Full application/proposal submission: Full applications/proposals must be submitted through Grants.gov.



All pre-application/proposal and full application/proposal components must be submitted by the deadlines stipulated on the first page of the Broad Agency Announcement. Failure to meet any of the deadlines will result in application/proposal rejection.

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

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

III. PRE-APPLICATION/PROPOSAL SUBMISSION

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



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

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

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

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/Proposal Submission



For specific instructions regarding content of the pre-application/proposal submission components, refer to section II.D.2.a, Pre-Application/Proposal Submission, in the Broad Agency Announcement.



All pre-application/proposal components must be submitted through eBRAP by the deadline specified on the first page of the Broad Agency Announcement.

To start a new pre-application/proposal, select the "New Pre-Application" link associated with the relevant program and award mechanism and follow the prompts in eBRAP. Information used to identify the pre-application/proposal will be requested at this step, including application title, keywords, and research characteristics.

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

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

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

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

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

Select the performing organization (site/organization at which the PI will perform the proposed work) and the contracting organization (awardee 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/proposal to be submitted.

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

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

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



No member of the Programmatic Panel may be named as a Collaborator or Key Personnel for the proposed research project, nor found to have assisted in the pre-application/proposal or full application/proposal processes. Refer to the Broad Agency Announcement for a link to the list of Programmatic Panel members.

Tab 4 – Conflicts of Interest: To avoid conflicts of interest during the screening and review processes, list all individuals, other than collaborators and key personnel, who may have a conflict of interest in the review of the application/proposal, 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 Broad Agency Announcement. Pre-applications/proposals where the components exceed the specified page limits may be rejected, or excess pages deleted from the file. Refer to the specific Broad Agency Announcement for detailed instructions. Documents should conform to the formatting guidelines outlined in [Appendix 2](#).

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

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



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

IV. FULL APPLICATION/PROPOSAL SUBMISSION

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/offeror 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/proposal 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/proposal 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/proposals will be rejected by Grants.gov if: (1) the organization’s Entity registration in SAM is not active; or (2) during the SAM registration process, the organization did not answer “Yes” when asked “Do you want to be eligible for grants and other federal assistance?”

2. Obtain Commercial and Government Entity (CAGE) Code

The applicant/offeror 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 three business days after the EIN or TIN is validated.

3. Register an AOR

An AOR is the Business Official designated as a member of the Grants.gov Workspace grant team who is authorized to submit the completed Workspace full application/proposal package. At the time of application/proposal submission to Grants.gov, the AOR certifies that, to the best of their knowledge, all information provided in the application/proposal is current, accurate, and complete. For applications/proposals submitted through Grants.gov, the name of the AOR

submitting the application/proposal is inserted into the application's/proposal'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/proposals on behalf of the organization. After the E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.



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

4. Create Grants.gov Workspace

Applicants/offerors must create a Grants.gov Workspace, which allows the application/proposal components to be completed online and routed through the applicant/offeror organization for review prior to submission. Once the Workspace has been created, participants (grant team members) can be added, and the required forms can be completed and reviewed before submitting. Specific information regarding the application/proposal process through Grants.gov Workspace can be found on the “Apply For Grants” page of Grants.gov (www.grants.gov/applicants/grant-applications/how-to-apply-for-grants).

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

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



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

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

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

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

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

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

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

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

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

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



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

- **Block 4b – Agency Routing Identifier.** Not applicable.
- **Block 4c – Previous Grants.gov Tracking ID.** For changed/correct full applications/proposals, enter the Grants.gov Tracking Number for the original application/proposal.
- **Block 5 – Applicant Information.** Enter the information for the applicant/offeree 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/offeree 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/proposal.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. Actual start and end dates will be determined during negotiations if the application/proposal is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant/offeree organization is outside the United States, enter 00000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the application/proposal. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.
- **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/offeror AOR organization’s authorized representative. The “Signature of Authorized Representative” is automatically completed upon submission of the Grants.gov application/proposal package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.



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

(b) Attachments Form

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

Each attachment in the Attachments Form must be uploaded as an individual PDF in accordance with the formatting guidelines listed in [Appendix 2](#). For all attachments, ensure that the file names are consistent with the guidance in the Broad Agency Announcement and below. Grants.gov will reject attachments with file names longer than 50 characters or incompatible file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, 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/proposal package may not exceed 200 MB. Applicants/offerors must contact the Grants.gov Contact Center (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/proposal package, including the Project Narrative.



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

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 Broad Agency 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/proposal. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) 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/proposal.



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

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/proposal may be administratively withdrawn. ***Letters of support not requested in the Broad Agency Announcement, such as those from members of Congress, will be removed from the application/proposal package.***

DOD Data Management Plan: DOD Data Management Plans have specific basic requirements, as described in Section 3.c., Enclosure 3, and therefore applicants/offerors 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 Broad Agency 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/offerors are strongly encouraged to use the suggested SOW format stated in the Broad Agency Announcement. Templates for SOW formats are available on the eBRAP “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 DOD 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>.

- **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 awardee's or the subawardee's capitalization threshold for financial statement purposes. Applicant/offeror organizations are encouraged to provide all equipment necessary to conduct the proposed research project.

Materials and Supplies: "Materials and Supplies" 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/offerors are responsible for budgeting all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DOD per diem rates. Note, military and federal civilian travel costs, unless funded via a project order, cannot not be subjected to fees/indirect costs.

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

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

Subaward/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 Subaward/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/offerors performing research outside of the United States should also include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Foreign currency exchange rates for applicants/offerors performing research outside of the United States will be determined at the time of application/proposal submission.

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

Equipment: If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested

equipment must describe, as applicable: (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; and (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 awardee with awardee 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/proposals 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/proposals that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:

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

(c) Research & Related Personal Data

Each application/proposal must include this form with the name fields of the Project Director (PD)/PI and any Co-PD(s)/Co-PI(s) completed; however, provision of the demographic information in the form is voluntary. If completing the form for multiple individuals, each Co-PD/Co-PI can be added by selecting the “Next Person” button. The demographic information, if provided, will be used for statistical purposes only and will not be made available to reviewers. Applicants/offers 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/proposal PI, in the “PROFILE – Project Director/Principal Investigator” section, enter the PI’s User Name provided by eBRAP into the data field labeled “Credential, e.g., agency login” (Green Box, Figure 1). Additional senior/key persons can be added by selecting the “Next Person” button.

A biographical sketch and full description of each PI and Senior/Key Person’s 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 Broad Agency 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/offeror 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 Broad Agency Announcement. *A budget justification for the entire period of performance must be uploaded to [Section I](#) 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. In addition, cost realism will be performed for cost type contracts. At the time of application/proposal submission to Grants.gov, the AOR is certifying to the best of their knowledge that all costs are current, accurate, and complete. The government reserves the right to request and require any additional information and documentation after it makes the type of award instrument determination, to include certified cost or pricing data if a procurement contract is awarded (FAR 15.403-4).



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

Budget Regulations and Restrictions:

- **Administrative and Cost Principles:** Awardees 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
 - Defense FAR Supplement (DFARS) Part 231



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

- **Maximum Obligation:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost of Preparing Applications/Proposals:** The cost of preparing applications/proposals in response to a Broad Agency Announcement is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications/proposals may be an allowable cost that can be included in the indirect/facilities and administrative (F&A) cost as specified in the organization’s applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars.
- **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 awardee 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 awardee 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/proposal submission. A timeline for execution of the agreement should be included within the project's SOW.

- **Pre-Award Costs:**
 - **Other Transaction Agreements:** An organization may request and negotiate pre-agreement costs with the assigned Agreements Officer.
 - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. An advanced agreement must be executed by the Contracting Officer prior to incurring any cost. Advanced Agreement Costs (Pre-Contract Costs) are referenced in FAR 31.205-32 and Advanced Agreements in 31.109.
 - **Assistance Agreement Awards:** If an application/proposal 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 awardee 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 awardee 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/proposal.

Section A: Senior/Key Person

- **Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant/offeror organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant/offeror organization should be included on the Research & Related Subaward Budget Attachment(s) Form. Consultant costs should be listed under Section F.3 of the Research & Related Budget Form (Other Direct Costs, Consultant Services).
- **Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. ***For most federal agencies, funding cannot be applied toward federal salaries and therefore these salaries should not be included in the requested budget.***
- **Level of Effort (Calendar, Academic, and Summer Months):** For each senior/key person, including unpaid personnel, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the application/proposal is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
- **Project Role:** Identify the role of each senior/key person listed.

Section B: Other Personnel

- **Number of Personnel:** For each project role category, indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category.
- **Level of Effort (Calendar, Academic, and Summer Months):** For each project role category, demonstrate the level of effort by listing the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period. *For most federal agencies, funding cannot be applied toward federal salaries and therefore these salaries should not be included in the requested budget.*
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the application/proposal is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement, other federally approved rate agreement, or other policy document).
- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

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

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

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

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

Section F: Other Direct Costs

- 1. Materials and Supplies:** “Materials and Supplies” 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 Broad Agency Announcement.

Section H: Indirect Costs. The indirect costs category may include F&A costs, overhead, General and Administrative (G&A), and other. The most recent federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a federal agency, indicate the source of the approval. *No budget will be approved by the government using an indirect rate exceeding the organization's negotiated rate.*

For assistance agreements, 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 awardee or subawardee. For contracts, statutory limits for fees are specified in FAR 15.404-4(c)(4).

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/offers 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/offers performing research outside of the United States will be determined at the time of application/proposal submission.

- **Personnel:** Identify the role of each senior/key person listed and describe their specific functions in the budget justification. Identify and explain any proposed adjustments to labor rates or salaries.
- **Equipment:** If equipment is requested, provide a detailed list showing the cost of each item and a rationale for the stated costs. The budget justification for any requested equipment must describe, as applicable: (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 and (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 awardee with awardee 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 USAMRAA warranted official. 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 assuring that the requested computer/software will be purchased in accordance with applicable cost principles.
- **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/proposals 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, the CDMRP does not intend to use funds from future fiscal year(s), if appropriated, to support the award.*
- **Foreign Collaboration Justification:** Applications/proposals that propose consultant, subaward, consortium, or contractual arrangements with foreign organizations or collaborators employed by foreign organizations/governments are required to demonstrate how one or more of the following conditions have been met:
 - The foreign organization or individual(s) employed by foreign organizations/governments contributes unique expertise, organizational capability, facilities, data resources, and/or access to a geographic location or population not generally available to investigators based in the 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 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 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 Broad Agency Announcement.

C. Submission to Grants.gov



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

All applications/proposals must be received by the deadline indicated on the first page of the respective Broad Agency 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/proposal is successfully received by Grants.gov. The applicant/offeree AOR will receive an acknowledgement of receipt and a Tracking Number (GRANTXXXXXXXX) from Grants.gov with the successful transmission of the application/proposal. Applicant/offeree AORs will also receive the official date/time stamp and Grants.gov Tracking Number in an email serving as proof of the application’s/proposal’s timely submission. The submission of a Workspace package can be tracked from the Workspace or by visiting Grants.gov (<https://grants.gov/applicants/grant-applications/track-my-application>) and entering the Tracking Number.

D. Verification of Grants.gov Submission in eBRAP

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



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

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



The full application/proposal submission deadline and the end of the submission verification period are stated on the first page of the Broad Agency Announcement (Section I, Overview of the Funding Opportunity).

APPENDIX 1

AWARDEE QUALIFICATION AND RESTRICTION INFORMATION

A. Awardee Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified awardees only. According to the standards of Department of Defense Grant and Agreement Regulations (DoDGARs) 22.415, a potential qualified awardee 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 awardee; (3) have a satisfactory record of integrity and business ethics; and (4) be otherwise qualified and eligible to receive a grant or cooperative agreement under applicable laws and regulations (see DoDGARs 22.420[c]). For contracts, please refer to FAR 9.104-1.

The 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/offeree that is available in SAM.

B. Eligibility Information

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

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

administrative proceedings that Section 872(c) describes. Reference Federal Register Notice, Vol. 80, No. 140, Wednesday, July 22, 2015.

In addition, per National Defense Authorization Act of Fiscal Year 2021, Section 1062, beginning October 1, 2024, DoD may not fund institutions of higher education (as defined by 20 USC 1002) that host a Confucius Institute, other than amounts provided directly to students as education assistance, unless a waiver is provided. A Confucius Institute is defined as a cultural institute directly or indirectly funded by the Government of the People's Republic of China.

General eligibility for investigators, organizations, and agencies:

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

C. J-1 Visa Waiver

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

Additional information on J-1 Visa Waivers can be located at the following Department of State website: <https://travel.state.gov/content/travel/en/us-visas.html>.

A. Conflict of Interest

Contract Awards: Organizational and Consultant COIs: Contracts must comply with the requirements found in FAR 9.5, Organizational and Consultant Conflicts of Interest. An organizational COI may result when factors create a potential or actual COI, or when the nature of the work to be performed creates a potential or actual COI on future acquisitions and some restrictions on future activities of the contractor may be required. FAR 9.5 will be used as a guide in analyzing and resolving organizational and consultant COIs relating to an award.

All COIs on the part of an organization or individual investigators that could bias the research results must be disclosed in the application/proposal, along with a plan to resolve them. An

award may not be made if it is determined by the Contracting Officer that a COI cannot be avoided or managed.

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

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

D. 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/proposal.

APPENDIX 2 FORMATTING GUIDELINES

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

- **Document Format:** Each attachment to the full application/proposal forms must be uploaded as an individual file in the format specified in the Broad Agency Announcement. All contributors to the application/proposal must use matching compatible versions of Adobe software for all PDF documents when editing and preparing application/proposal components. The use of different software versions will result in corruption of the submitted file.
- **Font Size:** 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/proposal 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/proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application/proposal are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Broad Agency Announcement (e.g., foreign transcripts submitted with English translations).

- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Individual attachments should be no larger than 20 MB. *If the file size for the entire Grants.gov application/proposal package will or may exceed 200 MB, applicants/offerors should contact the Grants.gov Contact Center (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/offerors 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/proposal is not recommended for funding and the applicant/offeror believes a factual or procedural error occurred during the review of the application/proposal, the organization or PI may submit an inquiry through the eBRAP Help Desk at help@eBRAP.org within 15 business days after the notification letter is sent. Inquiries submitted after 15 business days will not be considered.

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

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

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

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

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

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

APPENDIX 4

USE OF DOD OR 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/proposal submission, the government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

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

APPENDIX 5 RESEARCH BIOSAFETY REQUIREMENTS

Safety and Environment Requirements: In certain instances, safety and environment compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include 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), or pesticides outside of an established laboratory. *Applicants/offerors do not need to address these requirements in the initial application/proposal* unless instructed otherwise in the Broad Agency Announcement. PIs and organizational representatives will receive award-specific instructions if/when the application/proposal is recommended for funding.

Additional information is available at https://mrhc.health.mil/index.cfm/resources/researcher_resources/safety

If applicants/offerors 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 awardee 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 awardee 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/offeror organizations **may not commence performance** of research involving any of the above until regulatory documents are submitted **and** approved by the respective USAMRDC OHARO office(s) to ensure that DOD regulations are met. All expectations described below are consistent with 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/proposal submission, unless otherwise noted in the Broad Agency Announcement. PIs and organizational representatives will receive award-specific instructions if/when the application/proposal is recommended for funding. Applicants/offerors are encouraged to review the “Guide for Funded Investigators” 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://mrhc.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://mrhc.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).

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.

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).

A. Human Subjects Research

Applicants/offerors should keep in mind the following key requirements as they plan any DOD-funded human subjects research. Additional information is provided in the “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 protected health information may be disclosed.
- **10 USC 980 Waiver:** If the applicant/offeror 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/offeror 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). 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. LSGD efforts must undergo security review and additional approvals by the USAMRDC OHARO, USAMRDC Headquarters, and DOD Office of Human Research Protections to ensure the adequacy of the proposed administrative, technical, and physical safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors. DOD-funded research involving LSGD collected from DOD-affiliated personnel may require that the performer obtain 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/proposal submission or award negotiation. The lead institution responsible for

developing the master protocol and master consent form should be identified and should be the single POC for regulatory submissions and requirements.

Research Involving 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 and 21 CFR 312 and/or 21 CFR 812, as applicable.

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 (ACTs) 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/proposal, 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 of an ACT are required to register, i.e., Controlled clinical investigations (other than phase 1 investigations) of any U.S. Food and Drug Administration (FDA)-regulated drug or biological product for any disease or condition and certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric post-market surveillances of a device product. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85. PIs conducting phase 3 clinical trials shall submit results of analyses of group differences on the basis of sex/gender, race, and/or ethnicity to clinicaltrials.gov at the time of final report submission. If final analyses of sex/gender and race/ethnicity are not available at the time of the final technical report, a justification and plan ensuring completion and reporting of the analyses must be submitted to USAMRAA.

Posting of Informed Consent Forms: For each study that meets the definition of a **clinical trial**, i.e., a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes, conducted or supported by a federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee conducting the trial on a publicly available federal website. The recommended location is clinicaltrials.gov. The informed consent form must be posted on the federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

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

Note that the definition of experimental subject is found in DoDI 3216.02 and has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an experimental subject in a DoD-supported experiment unless participation in the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo or usual care arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements.

Research Involving Use of 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 is 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, non-profit repositories, etc.). Additional approvals are required for research with fetal tissues in accordance with DoD Instruction 3216.02. The OHRO will coordinate these reviews; investigators should allow for additional time to receive OHRO approval.

Research Involving Use of Human Embryos: The OHRO adheres to the NIH policy requirements and requires submission and review of research on existing human embryonic stem cell lines and derivation of new human embryonic stem cell lines. Due to the ethical issues related to research use of embryonic stem cells, OHRO recommends investigators who plan to conduct research with embryonic stem cells consult the OHRO for input during the proposal process. As part of the OHRO submission, investigators should provide the NIH registration numbers for the use of human embryonic stem cell lines. Note: DoD funds cannot be used to support or be used for the creation of a human embryo or embryos for research purposes (to include gene editing research) or for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of suffering, injury, or death greater than that allowed for research on fetuses in utero.

Research With Children Conducted Outside the U.S.: Note that in addition to host nation and local requirements, U.S. research regulatory requirements apply when DOD-funded research is conducted outside the U.S. Applicants who will conduct research outside the U.S. with subjects who have not reached the age of majority are encouraged to consult with OHRO in advance of submitting their study to the IRB or Ethics Committee so that these regulatory differences can be addressed.

APPENDIX 7 ADMINISTRATIVE INFORMATION

A. Disclosure and Marking of Proprietary Information

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

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

B. Classified Information, Data, or Outcomes

In accordance with 32 CFR, Section 2002.4, inclusion of classified research data within the application/proposal and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns is disallowed and may result in application/proposal withdrawal. Classified is defined as information that has been determined pursuant to Executive Order 13526 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/Proposal Information

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

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/proposals 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 Assistance Agreement: Organizational transfer of an award is discouraged and will be considered on a case-by-case basis. If approved, the PI's original organization will be required to agree to relinquish the award. The new organization will be required to resubmit the entire application/proposal on behalf of the PI, including regulatory documentation. Extended times for transfer may put the award funding at risk. A transfer will not, unless under extraordinary circumstances, be allowed for any organization that includes a clinical trial at its location. Organization transfers are not allowed in the last year of the performance period.

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

Transfer of an Other Transaction Agreement (OTA): Transfer of an OTA award to a new organization is not permitted.

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

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/proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by 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

Awardees 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.)
- (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.)

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

Contracts: Reference FAR Part 45 and DFARS Part 245. Contractors are ordinarily required to furnish all property necessary to perform Government contracts in accordance with FAR 45.102(a).

Assistance Agreements: Unless otherwise specified in the award, the title to equipment or other tangible property acquired with government funds will vest in institutions of higher education, nonprofit, and for-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient, if vesting will facilitate scientific research performed by the organization for the government. However, if the award is subsequently transferred to a new organization, the DOD reserves the right to require the transfer of equipment acquired with the award funds to the federal government or to an eligible third party.

K. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (35 USC 200 et seq.), the awardee and collaborators may elect to retain title to their subject inventions and technical data, subject to meeting the reporting and patent filing requirements and retained rights to the 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.

The FAR and DFARS govern the disposition of technical data rights, and generally the ownership of technical data is determined by the funding that governs it. For additional information, reference:

Contracts: FAR part 27 and DFARS Part 227

Assistance Agreements: 2 CFR 200.315-316

L. Award Notices

The USAMRDC executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the government will be determined by the government prior to award, in accordance with the Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, which provides the legal criteria to select a procurement contract or an assistance agreement.

- 1. A procurement contract** is required when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the U.S. government (31 USC 6303). The award type, along with the start date, will be determined during the negotiation process.
- 2. An assistance agreement (grant or cooperative agreement)** is appropriate when the U.S. government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of

the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

3. An **“Other Transaction”** will also be considered as a vehicle for award under this BAA, in accordance with 10 USC 4021 and 10 USC 4022. The OT authorities were created to give DOD the flexibility necessary to adopt and incorporate business practices that reflect commercial industry standards and best practices into its award instruments. When leveraged appropriately, OTs provide the government with access to state-of-the-art technology solutions from traditional and non-traditional defense contractors (NDCs), through a multitude of potential teaming arrangements tailored to the particular project and the needs of the participants. OTs can help to foster new relationships and practices involving traditional and NDCs, especially those that may not be interested in entering into FAR-based contracts with the government; broaden the industrial base available to government; support dual-use projects; encourage flexible, quicker, and cheaper project design and execution; leverage commercial industry investment in technology development and partner with industry to ensure DOD requirements are incorporated into future technologies and products; and collaborate in innovative arrangements. OTs are not FAR-based procurement contracts, grants, cooperative agreements, or cooperative research and development agreements.

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

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 awardee 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/proposal is recommended for funding, there are several types of reporting requirements that may be required per the terms and conditions of the specific award. The award document will specify the nature and frequency of reports, i.e., financial, technical, annual, quarterly, etc. All awards will require, at a minimum, annual and final technical reports. Detailed descriptions of the reporting requirements can be found on the USAMRDC Technical Reporting Requirements website at https://mrhc.health.mil/index.cfm/resources/researcher_resources/reporting/technical.

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

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

Service Contract Reporting (SCR): SCR is now a requirement of all DOD contracts. Offerors are allowed to include a nominal fee in their cost/price application/proposal for providing this

data. A “nominal fee” is defined as a computation of an administrative assistant-equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. SCR costs/price will not be evaluated as part of the total evaluated application/proposal cost/price.

The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to report the information outlined in DFARS 252.204-14, or DFARS 252.204-15, for services performed during the preceding government fiscal year under the contract or order that exceed the thresholds established in FAR 4.1703(a)(2), using the following web address: <https://www.sam.gov/SAM>.

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

APPENDIX 10 ACRONYM LIST

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| 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 | U.S. Centers for Disease Control and Prevention |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| CRADA | Cooperative Research and Development Agreement |
| CRRP | Combat Readiness - Medical Research Program |
| 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 |
| GSI | General Submission Instructions |
| GSA | General Services Administration |
| HIPAA | Health Insurance Portability and Accountability Act |

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| 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 |
| SCR | Service Contract Reporting |
| SF | Standard Form |
| SOW | Statement of Work |
| 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 |