

General Submission Instructions

Fiscal Year 2015

Department of Defense

U.S. Army Medical Research and Materiel Command

Broad Agency Announcement for Extramural Medical Research

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This General Submission Instructions document consists of two documents containing instructions on how to prepare and submit a proposal/application. The second document, the Broad Agency Announcement, is available for downloading from Grants.gov.

I. HELPFUL INFORMATION

A. Tips for Success



This symbol marks helpful hints throughout this document.



This symbol refers to the Funding Opportunity Announcement/Broad Agency Announcement for specific instructions.

B. Current Funding Opportunity Announcement

The Fiscal Year 2015 U.S. Army Medical Research and Materiel Command's (USAMRMC) Broad Agency Announcement (BAA) can be found by searching Grants.gov (<http://www.grants.gov/>) using the announcement number **W81XWH-BAA-15-1** or the Catalog of Federal Domestic Assistance (CFDA) number **12.420**.

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

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

C. Receiving Emails from the CDMRP, eBRAP, and Grants.gov

To help ensure that all email correspondence is delivered correctly and is not treated as spam by email programs, keep your email address up to date in eBRAP and Grants.gov and place the following domains into your safelist: army.mil, us.army.mil, *.mail.mil, eBRAP.org, and grants.gov.

D. Agency Contacts

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

Phone: 301-682-5507

Email: help@eBRAP.org

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

Phone: 800-518-4726

Email: support@grants.gov

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both: (1) pre-proposal/pre-application submission through eBRAP (<https://eBRAP.org/>); and (2) full proposal/application submission through Grants.gov (<http://www.grants.gov/>), with proposal/application status available on eBRAP.

A. Submission Dates and Times

This BAA is continuously open for a 12-month period, from October 1, 2014 through September 30, 2015. **Pre-proposals/pre-applications are required** and may be submitted at any time throughout the 12-month period.

1. Pre-Proposal/Pre-Application Submission through eBRAP

All pre-proposals/pre-applications must be submitted through eBRAP (<https://eBRAP.org/>). A registration process through eBRAP (<https://eBRAP.org/>) must be completed before a pre-proposal/pre-application can be submitted.

2. Full Proposal/Application Submission through Grants.gov

A PI must be invited to submit a full proposal/application. An invited full proposal/application must be submitted electronically through Grants.gov (<http://www.grants.gov/>). Proposals/Applications will not be accepted by mail or in person.

To apply through Grants.gov, an organization must complete the Grants.gov registration process. Allow up to 4 weeks for the completion of the Grants.gov registration process. You are advised to register early.

Foreign organizations doing business outside of the U.S. are also required to complete the Grants.gov registration process, in addition to fulfilling supplementary requirements for doing business with the U.S. federal government.

If business is conducted with the federal government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a Data Universal Numbering System (DUNS) number or registration as an Entity in the System for Award Management (SAM). Detailed information, automated tools, and checklists are available at <http://www.grants.gov/web/grants/applicants/organization-registration.html>.

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

a. DUNS Number

The applicant organization and all subrecipient/subawardee organizations must have a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet. If an organization does not have a DUNS number, an authorized business official of the organization can request one by calling 866-705-5711 or by registering online (<http://fedgov.dnb.com/webform/displayHomePage.do>). Organizations located outside of the U.S. can request and register for a DUNS number on line via web registration (<http://fedgov.dnb.com/webform/displayHomePage.do>). Web registration can take 1-2 business days.

b. SAM Registry

The applicant organization must be registered as an Entity with the SAM (<https://www.sam.gov>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. The SAM validates organization information and electronically shares the secure and encrypted data with federal agencies’ finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an Accounts Receivable point of contact (POC), an Electronic Business POC, and a Government Business POC during the SAM registration process. ***Entity registrations in SAM have an annual expiration. Verify the status of your organization’s Entity registration in SAM well in advance of the application submission deadline.*** An organization can register in SAM online at <https://www.sam.gov>. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1 to 3 days. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the U.S. Internal Revenue Service. If you have the necessary information, online SAM registration will take about 1 hour to input, depending upon the size and complexity of your organization. Allow 3 to 4 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>.***

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

c. Commercial and Government Entity (CAGE) Code

The applicant organization must have a CAGE Code. The Defense Logistics Information Service in Battle Creek, Michigan, is the only authorized source of CAGE Codes. CAGE Codes will be assigned to registrants as their SAM registration goes through the validation process. Foreign registrants in SAM must be assigned a NATO CAGE Code (NCAGE). An NCAGE code can be obtained by contacting the National Codification Bureau of the country where the company is located or by connecting to Form AC135 (http://www.xmarks.com/site/www.dlis.dla.mil/Forms/Form_AC135.asp). On average, CAGE Code or NCAGE Code validation in SAM occurs within 3 business days after the TIN is validated.

d. Authorized Organizational Representative (AOR)

Each organization must have an AOR who is registered with Grants.gov. Individual Principal Investigators do not register with Grants.gov; the Authorized Organizational Representative (AOR) is required to register. An organization’s E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before submitting an application, an organizational representative must register to submit on behalf of the organization at Grants.gov (<http://apply07.grants.gov/apply/OrcRegister>).

An AOR must first register with the Grants.gov credential provider at <http://apply07.grants.gov/apply/OrcRegister> to obtain a username and password. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Biz POC for assignment of user privileges. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

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

On occasion, the USAMRMC may update or change the proposal/application package (hereinafter, application package) in Grants.gov. The applicant must use the latest version of the Grants.gov application package; proposals/applications submitted with a different version of the application package will not be accepted by Grants.gov. *Sign up in Grants.gov (<http://www.grants.gov/>) for “Send me change notification emails” by following the link on the Synopsis page for the BAA or by responding to the prompt provided by Grants.gov when first downloading the application package.*



Submission of proposals/applications from federal agencies and those proposing collaborations with Military Facilities have unique requirements. Budget requirements and restrictions apply. Refer to [Section II.C.5., Research & Related Budget](#), for additional information.

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



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



All pre-proposal/pre-application components must be submitted through eBRAP (<https://eBRAP.org/>). Remember to press the “Submit” button to finalize the pre-proposal/pre-application.

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

Tab 1 – Application Information: Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

Tab 2 – Application Contacts: Enter contact information for the PI and the organization’s Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 form. **The Business Official must either be named or invited in order for the preproposal/pre-application to be submitted.**

If the organization’s Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. eBRAP does not require approval of the pre-proposal/pre-application by the PI’s organization.

Tab 3 – Collaborators and Conflicts of Interest (COIs): Enter the name, organization, and role of all collaborators and key personnel associated with the application.



The USAMRMC does not follow National Institutes of Health (NIH) guidelines for role designation of project participants. Applicants should assign the role of each participant in accordance with the participant’s respective involvement in the project.



Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in any pre-proposal/pre-application and full proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable; however, those Military Facility personnel are prohibited from being involved in the review process and/or with making funding recommendations.***

To avoid COIs during the screening and review processes, enter all individuals outside of the proposal/application who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship).

To preserve the integrity of its peer and programmatic review processes, the USAMRMC discourages inclusion of any employee of its review contractors in proposals/applications for funding. For FY15, the peer review contractor is SRA International, Inc. The programmatic review contractor is Leidos, Inc. Proposals/Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to resolve COIs are provided and deemed appropriate by the Government. Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to [Appendix 1](#) for additional information.

Tab 4 – Required Files: Upload all documents as specified in the BAA. Documents should conform to the formatting guidelines outlined in [Appendix 2](#).

- eBRAP will truncate characters exceeding the limit specified for each data field as specified in the BAA.
- eBRAP will not allow a document to be uploaded in the Required Files tab if the number of pages exceeds the limits specified in the BAA.

Tab 5 – Submit Pre-Application: Enter password in the space provided next to “Enter Your Password Here” and press the “Submit” button. Press the “Confirm Submission” button to complete the pre-proposal/pre-application submission.

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

C. Content and Form of Proposal/Application Submission

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

A compatible version of Adobe Reader must be used to view, complete, and submit the Grants.gov application package. ***Grants.gov will reject an application package that is opened at***

any time by an individual with an incompatible version of Adobe Reader. Rejected proposals/applications must be resubmitted using a new application package and a supported version of Adobe Reader.

The USAMRMC cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov. It is the applicant's responsibility to verify his/her Adobe Reader's compatibility with Grants.gov: <http://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-compatibility.html>. A no-cost compatible version of Adobe Reader can be downloaded at http://www.grants.gov/help/download_software.jsp. *Resubmission of a proposal/application prior to the Grants.gov deadline must be coded as a "Changed/Corrected Application."*

Verification of Grants.gov proposal/application in eBRAP:

The ability to view and modify the Grants.gov application in eBRAP is contingent upon an organization, its Business Officials, and its PIs registering and being affiliated in eBRAP. eBRAP registration instructions are available in the user guide at <https://ebrap.org/eBRAP/public/UserGuide.pdf>.

For invited full proposals/applications, following eBRAP retrieval and validation of the Grants.gov application, eBRAP will notify the organizational representatives and PI to log into eBRAP to review, modify, and verify the Grants.gov proposal/application submission. eBRAP will validate retrieved files against the BAA requirements and discrepancies will be noted in both the email and in the Full Application Files tab. eBRAP does not confirm the accuracy or completeness of file content. *It is the applicant's responsibility to review all proposal/application components.*



The PI will have a period of 5 days from the date of proposal/application submission to Grants.gov, i.e., *the verification period*, to complete this process. Once the verification period has ended, the PI will not be able to modify proposal/application components. *If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID.*

The proposal/application consists of the following components:

1. eBRAP Log Number

During the pre-proposal/pre-application process, each submission will be assigned a unique log number by eBRAP in the following format: BA15xxxx. The corresponding Grants.gov application package must be submitted using this unique eBRAP log number. Enter the eBRAP log number in one of two ways:

- **Manual Entry:** Fill in the **Application Filing Name** on the first screen of the Application Package (Figure 1) using only the **eBRAP log number** (e.g., BA15xxxx) assigned during the pre-proposal/pre-application process.

- **System-to-System Entry:** If a system-to-system interface with Grants.gov is being used, enter the eBRAP log number acquired during the pre-proposal/pre-application process into the **Submission Title** field.

Figure 1. Manual Entry of eBRAP log number in Grant Application Package

Agency Contact:	CDMRP Help Desk 301-682-5507 help@eBRAP.org
<hr/> This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.	
Application Filing Name:	Enter eBRAP log number here

2. SF 424 (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 this application package. See below for clarification to general instructions:

- **Block 1 – Type of Submission.** For original submissions, select the “Application” box. For changes that must be made after the original submission, the complete package must be resubmitted with the “Changed/Corrected Application” box selected.
- **Block 2 – Date Submitted.** Enter the date the proposal/application is submitted.
Applicant Identifier. Enter the submitting organization’s Control Number, if applicable. If there is no Organization Control Number, leave this field blank.
- **Block 3 – Date Received by State and State Application Identifier.** Not applicable.
- **Block 4 – a. Federal Identifier Box.** This box will be populated by Grants.gov for an original application.
- **Block 4 – b. Agency Routing Identifier.** Not applicable.
- **Block 4 – c. Previous Grants.gov Tracking ID.** For changed/corrected proposals/applications, enter the Grants.gov tracking number (the federal Identifier Number assigned to the original proposal/application).
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. “Person to be contacted on matters involving this application” is the Business Official.
- **Block 6 – Employer Identification.** Enter the Employer Identification Number (EIN) or Tax Identification Number (TIN) as assigned by the Internal Revenue Service. If applying from an organization outside the U.S., enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select “New” for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.

- **Block 11 – Descriptive Title of Applicant’s Project.** Enter the same project title as used for the pre-proposal/pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. The estimated end date should reflect the time needed to successfully complete the proposed project and not exceed 5 years. Actual start and end dates will be determined during negotiations if the proposal/application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the U.S., enter 00-000.
- **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of the proposal/application. If outside the U.S., 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 and be consistent with the pre-proposal/pre-application 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.
- **Block 18 – SFLLL (Disclosure of Lobbying Activities) or Other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL to disclose lobbying activities pursuant to Title 31 United States Code Section 1352 (31 USC 1352).
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization’s authorized representative. The “Signature of Authorized Representative” is not an actual signature and is automatically completed upon submission of the electronic application package.
- **Block 20 – Pre-Application.** Not applicable.
- **Block 21 – Cover Letter Attachment.** Not applicable.

3. Attachments Form

Grants.gov does not validate for the presence of attachments on this Attachments Form. Each attachment to the Grants.gov proposal/application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in [Appendix 2](#). For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire application package may not exceed 200 MB. Applicants must contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that a file exceeding the maximum size will be accepted or for other guidance.



For specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form, refer to the BAA.



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

The following must be included as attachments to this form:

Attachment 1: Project Narrative: Named “ProjectNarrative.pdf.” The Project Narrative is the main body of the proposal/application. The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. There is no form for this information. A detailed description of the research to be undertaken should be submitted. This should include the areas described in the BAA.

Attachment 2: Supporting Documentation: Combine and attach as a **single PDF file named “Support.pdf.”** Include only supporting documentation as indicated in the BAA. *The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.*



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



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

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

Attachment 4: Statement of Work (SOW): Named “SOW.pdf.” The SOW outlines and establishes the PI’s and an organization’s performance expectations for which USAMRMC may provide funding. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under Freedom of Information Act (FOIA).

A series of relatively short statements should be included describing the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award.



For specific instructions regarding the SOW content, refer to the BAA.

SOW format: There is no limit to the number of specific aims, tasks, or subtasks that are described within the SOW page limit. *The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The SOW must be in PDF format prior to attaching. The Government reserves the right to request a revised SOW format and/or additional information.*

Attachment 5: Impact/Outcomes Statement: Named “Impact.pdf.” Explain the potential impact of the research in the field, the significance of this impact, and when it can be anticipated. Explain how the results of this research are expected to impact the intended beneficiaries. Expound upon the dual (military and public) purpose for the research, as appropriate. For development of devices and technologies, include the potential translation, implementation, and/or commercial use for the product/technology being developed.

Attachment 6: Data- and Research Resource-Sharing Plan: Named “Sharing.pdf.” Describe how unique and/or final research data will be shared with the research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan.

Attachments 7-9: Additional Documents (as applicable): Attach each as a separate PDF file, named as indicated in the BAA (e.g., “Trans_Imp_Comm.pdf,” “COI.pdf,” “MFBudget.pdf,” etc.).



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

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

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

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

Figure 2. PI's eBRAP User Name.

PROFILE - Project Director/Principal Investigator

Prefix: * First Name: Middle Name:

* Last Name: Suffix:

Position/Title: Department:

Organization Name: Division:

* Street1:

Street2:

* City: County/ Parish:

* State: Province:

* Country: USA: UNITED STATES * Zip / Postal Code:

* Phone Number: Fax Number:

* E-Mail:

Credential, e.g., agency login:

Biographical Sketch Suggested Format: The suggested biographical sketch format is available in a Microsoft Word document on the “Funding Opportunities and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. Use of this document is optional. Each biographical sketch must be in PDF format prior to attachment.

- a. **PI Biographical Sketch:** This file must be titled “Biosketch_LastName.pdf,” where “LastName” is the last name of the PI.
- b. **PI Previous/Current/Pending Support:** This file must be titled “Support_LastName.pdf,” where “LastName” is the last name of the PI.

For all previous (award period of performance ending within the past 5 years), current, and pending research support, include the title, time commitments, supporting agency, name and address of the funding agency’s procuring Contracting or Grants Officer, performance period, level of funding, brief description of the project’s goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

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.

- c. **Key Personnel Biographical Sketches:** Each file must be titled “Biosketch_LastName.pdf,” where “LastName” is the last name of the respective individual.
- d. **Key Personnel Previous/Current/Pending Support:** Each file must be titled “Support_LastName.pdf,” where “LastName” is the last name of the respective individual. Refer to content requirements under “PI Previous/Current/Pending Support” listed above.

5. Research & Related Budget

An estimate of the total proposed research project costs, with a breakdown of all cost categories for each year, must be submitted on the Grants.gov Research & Related Budget form. ***Include a sufficiently detailed budget and budget justification*** so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1. At the time of proposal/application submission to Grants.gov, the Authorized Organizational Representative is certifying to the best of his/her knowledge that all costs are current, accurate, and complete.

Budget Regulations and Restrictions

- **Administrative and Cost Principles.** Applicants are required to comply with the following, as applicable:
 - Federal Acquisition Regulation (FAR) Part 31
 - Defense FAR Supplement Part 231
 - Department of Defense Grant and Agreement Regulations (DoDGAR) (32 CFR Subtitle A, Chapter 1, Subchapter C, Parts 21-37)
 - 2 CFR 220 (Code of Federal Regulations, Title 2, Part 220), “Cost Principles for Educational Institutions (Office of Management and Budget [OMB] Circular A-21)”
 - 2 CFR 225, “Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87)”
 - OMB Circular A-102, “Grants and Cooperative Agreements with State and Local Governments”
 - 2 CFR 215, “Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (OMB Circular A-110)”
 - 2 CFR 230, “Cost Principles for Non-Profit Organizations (OMB Circular A-122)” (For those non-profit organizations specifically excluded from the provisions of OMB Circular A-122, FAR 48 CFR Subpart 31.2 shall apply.)
 - OMB Circular A-133, “Audits of States, Local Governments, and Non-Profit Organizations”
- **Award Funding/Maximum Obligation:**
 - **Contract Awards:** Reference contract funding regulations in FAR part 32.7 and DFARs part 232.7.
 - **Assistance Agreement Awards:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

- **Pre-Award Costs:** Pre-award costs are allowable as follow:
 - **Contract Awards:** An organization may request and negotiate pre-contract costs prior to contract award. A pre-contract cost agreement must be executed by the Contracting Officer prior to incurring any cost. The costs incurred must be allowable and allocable under the resultant contract. Payment will not be made until a contract is awarded. If the parties are unable to reach agreement on the award of the proposed contract, the Government shall be under no obligation to reimburse the contractor for any costs incurred.
 - **Assistance Agreement Awards:** An institution of higher education or non-profit organization may, at its own risk and without the federal government’s prior approval, incur obligations and expenditures to cover costs up to 90 days before the 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, without the government’s prior approval. If specific expenditures would otherwise require prior approval, the recipient must obtain the Grants Officer’s approval before incurring the costs. Government prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period. For-profit organizations must obtain the Grants Officer’s approval prior to incurring any obligations and expenditures before the beginning date of the initial budget period of a new award.


The incurrence of pre-award costs imposes no obligation on the Government either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. The Government expects the contractor/recipient to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the organization’s ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project.

- **Cost of Preparing Proposals/Applications:** The cost of preparing proposals/ applications in response to this BAA is not considered an allowable direct charge to any resultant award. However, the cost of preparing proposals/applications may be an allowable expense included in the indirect/facilities and administrative cost as specified in the organization’s applicable cost principles and the FAR Part 31 and DFARs Part 231.
- **Currency:** All costs must be entered in U.S. dollars. Organizations performing research outside of the U.S. should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used.



Submit a detailed budget and justification that covers the entire period of performance (not just the first year). The Government reserves the right to request a revised budget and budget justification and/or additional information.

Budget Instructions: Complete the Research & Related Budget following the instructions below. Begin by entering the organizational DUNS number, Budget Type, Name of Organization, and anticipated start and end dates. *Ensure that the DUNS number is entered accurately or Grants.gov will reject the proposal/application. Federal agencies applying as the applicant organization are required to have a DUNS number.*

 *For all federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.*

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

For Collaborating Military Facilities: A proposal/application from an organization that includes collaboration with a Military Facility must submit Collaborating DoD Military Facility Budget Form(s) as instructed in [Section II.C.8., Collaborating with DoD Military Facilities](#).

Section A: Senior/Key Person

- 1. Prefix; First, Middle, and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under section F.3.
- 2. Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
- 3. Base Salary:** Enter the current annual base salary (based on a full-time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Labor rates or salaries may not be increased as a result of receiving an award. Identify and explain in the budget justification any proposed adjustments to rates or salaries. Any proposed increases in rates or salaries over the period of the award must be consistent with the applicable cost principles and organization's estimating procedures. *For most federal agencies, funding cannot be applied toward federal salaries; therefore, these salaries should not be included in the requested budget.*
- 4. Calendar, Academic, and Summer Months:** For each senior/key person, including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.
- 5. Requested Salary:** Enter the amount of salary requested for this budget period.
- 6. Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the proposal/application is

recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).

7. **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.
8. **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.

Section B: Other Personnel

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

Section C: Equipment Description: Equipment is any article of non-expendable tangible property to be charged directly to the award and having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit (unless the applicant organization's policy has established a limit lower than \$5,000). Applicant organizations are encouraged to provide all equipment necessary to conduct the proposed research project. If equipment is requested, provide a detailed list showing the cost of each item. The budget justification for any requested equipment must describe, as applicable:

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

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

Section D: Travel: Travel costs may include:

1. Costs to attend one or more scientific/technical meetings per year: Include the meeting name, purpose, location, and date, if known, in the budget justification. International travel may be requested but must be well justified and is subject to approval.
2. Costs for travel associated with the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included. International travel may be requested but must be well justified and is subject to approval.
3. Travel costs of military and DoD civilian employees that are approved for this project will be paid by the Government. No funds may be paid by the organization to any DoD civilian employee or military to cover such costs.
4. The PI may be required to participate in an In-Progress Review (IPR). The PI shall budget for, prepare for, and participate in an IPR, lasting not more than two days and including up to two overnight stays, for each year of the project's term, at the Contracting Officer's Representative's /Grants Officer's Representative's (COR/GOR) request. The invitation and format for the IPR will be provided by the COR/GOR at least (90) days prior to the meeting. The meetings will generally be held in the Fort Detrick, MD area but could occur elsewhere in the U.S.

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

Section F: Other Direct Costs

1. **Materials and Supplies:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For individual or total materials and supplies costing \$5,000 or more per year, provide additional breakdown. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.
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:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
4. **ADP/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification the provider's computer service rates. See [Section F.9., "Other Expenses"](#) for information regarding purchase of computers.

5. **Subaward/Consortium/Contractual Costs:** Include the total funds (direct and indirect costs) requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.
6. **For Military Facilities** collaborating in the performance of the project, a separate budget form and justification is required and submitted as an attachment. See [Section II.C.8., Collaborating with DoD Military Facilities](#), for more information.
7. **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
8. **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. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. Costs for the construction of facilities are not allowable.
9. **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule.

Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project. If a computer/software purchase is requested, include the following in the budget justification:

- Detailed explanation for why purchase of computer/software is required to complete the proposed research project.
- Statement verifying that the requested computer/software is not currently available for use by the PI.
- Statement assuring that the requested computer/software will be purchased in accordance with applicable cost principles.

Include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs: Include the total direct costs (A-F).

Section H: Indirect Costs: The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a federal agency, indicate the source of the approval.

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

Provide documentation to support the indirect cost rate (e.g., the current DHHS, DCAA, or ONR Rate Agreement, other federally approved rate agreement, or other policy document) via eBRAP (<https://eBRAP.org>).

If a negotiated approved rate(s) does not exist, provide sufficient detail for a proposed rate (adhering to the applicable cost principles) in the budget justification. Organizations can also visit the DHHS (<https://rates.psc.gov/fms/dca/negotiations.html>), the Office of Naval Research (<http://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx>), and the Defense Contract Audit Agency (<http://www.dcaa.mil/>) for additional information on indirect rates.

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

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

Section K: Budget Justification: Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to section K of the Research & Related Budget.

Proposals/Applications from **federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their expiration for obligation, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

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

6. Project/Performance Site Location(s) Form

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

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

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

A description of services or materials that are to be provided under the subaward is required. Organizations must provide sufficient detail and justification to enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

8. Collaborating with DoD Military Facilities

When a Military Facility will be a collaborator in performance of the project, complete a separate **“Collaborating DoD Military Facility Budget Form,”** including a budget justification, for each Military Facility.

A description of services or materials that are to be provided by the collaborating Military Facility is required. Applicant organizations must provide sufficient detail and justification to enable the federal government to determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

The contractor or recipient may provide resources to the Military Facility, such as personnel, supplies, or equipment, paid for/purchased using award funds. The resources to be provided should be identified in the proposal/application. These funds should be included in the applicant organization’s budget and not included on the collaborating Military Facility’s budget form.

If the Military Facility anticipates incurring costs, the Military Facility researcher must coordinate with his/her local Resource Management (RM) office (or equivalent) to prepare a sound budget and justification for the estimated costs. The Military Facility researcher should also coordinate with his/her technology transfer office, when applicable. Where there are no DoD-established reimbursement rates [e.g., institutional review board (IRB) fees, indirect cost rates, etc.], the Military Facility’s RM office (or equivalent) must provide details of how the proposed rates were determined. The Military Facilities’ direct and indirect costs to be supported when performing collaborative research with the contractor/recipient must meet the requirements of the DoD’s Financial Management Regulation (FMR) 7000.14-R. Note that military and DoD civilian employee travel costs cannot be paid with award funds.

If possible, the USAMRMC’s RM office will “direct fund” [via a Funding Authorization Document, Military Interdepartmental Purchase Request, or other authorized method] the collaborating Military Facility to support its costs to be incurred in performance of the Military Facility’s portion of the research project awarded to the applicant organization. When “direct funded,” these funds **will not** be included in the award amount to the contractor or recipient.

If extraordinary circumstances exist whereby the USAMRMC RM office is not able to “direct fund” the Military Facility, the contractor or recipient may provide award funds to the Military

Facility. The Military Facility, in conjunction with the applicant organization, must provide a written justification for this funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility, the associated costs, when the activities will take place, why “direct funding” is not possible, why the applicant organization cannot provide the necessary resources and/or services, the Comptroller’s (or equivalent) ability to accept and process award funds appropriately, etc. These funds would be included in the award amount to the contractor or recipient. Prior approval from the U.S. Army Medical Command, Principal Assistant Responsible for Contracting, is required under this funding method.

A cooperative research and development agreement (CRADA) or other instrument (as authorized by law or regulation) must be utilized for the contractor or recipient to provide award funds to the Military Facility. The CRADA (or other instrument) is not required at the time of proposal/application submission. A timeline for execution of the document will be established during negotiations.

APPENDIX 1

QUALIFICATION AND ELIGIBILITY INFORMATION

A. Recipient Qualification

To protect the public interest, the federal government ensures the integrity of federal programs by conducting business with qualified recipients only. To be qualified, a potential recipient must at least (1) have a satisfactory record of executing programs or activities under federal procurement or assistance or awards, if it is a prior recipient of such awards; (2) have a satisfactory record of integrity and business ethics; and (3) meet the qualifications and standards of the Federal Acquisition Regulations (FAR), Defense Federal Acquisition Regulations Supplement, and the Department of Defense Grant and Agreement Regulations.

The U.S. Army Medical Research Acquisition Activity (USAMRAA) utilizes the Exclusions within the Performance Information functional area of the System for Award Management (SAM), formerly the Excluded Parties List System (EPLS), to identify individuals and organizations unqualified to receive federal awards. More information about Exclusions reported in SAM is available at <https://www.sam.gov/>.

B. Eligibility Information

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. Investigators must meet the specific BAA requirements.
- **Eligible Organizations:** The USAMRAA makes awards to 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 U.S.:** Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded intramural programs. Such agencies are required to explain how their applications do not overlap with their intramural programs.

C. Conflict of Interest

All conflicts of interest (COIs) or potential COIs on the part of an organization or individual investigators that could bias the research project must be disclosed in the proposal/application submission, along with a plan to resolve them.

Contracts awarded under this BAA must comply with the requirements found in FAR Part 9.5 Organizational and Consultant Conflicts of Interest. An organizational COI may result when factors create an actual or potential COI, or when the nature of the work to be performed creates an actual or potential COI on future acquisitions and some restrictions on future activities of the

contractor may be required. FAR Part 9.5 will be used as a guide in analyzing and resolving organizational COIs relating to an award.

FAR Part 9.5 will also be used as a guide in analyzing and resolving organizational COIs relating to assistance agreements.

A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be resolved.

Post-Employment Conflict of Interest: There are certain post-employment restrictions on former federal officers and employees as defined in Section 207 of Title 18 United States Code and FAR Part 3.104-4(c). If an applicant believes a post-employment restriction or COI may exist, the situation should be discussed with the USAMRMC legal staff (301-619-7138) prior to expending time and effort in preparation of a proposal/application.

APPENDIX 2

FORMATTING GUIDELINES

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

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point, not condensed.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project Narratives and pre-proposal/pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** Inclusion of links to publications referenced in the proposal/application is encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the BAA (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB. *If the file size for the entire application package will or may exceed 200 MB, applicants should contact the Grants.gov Contact Center (support@grants.gov) for written confirmation that the file will be accepted or for other guidance.*

APPENDIX 3

ADMINISTRATIVE INFORMATION AND REQUIREMENTS

A. Disclosure of Proprietary Information

Do not include proprietary information in a pre-proposal/pre-application or abstract. Proprietary information should only be included in a full proposal/application if necessary for evaluation.

Proprietary information submitted in a proposal/application may be disclosed outside the government for the sole purpose of technical evaluation. Evaluators must agree that proprietary information in the proposal/application will be used for evaluation purposes only and will not be further disclosed or used.

All proposals/applications may be subject to public release under the Freedom of Information Act (FOIA) to the extent that they are incorporated into an award document; proposals/applications that are not selected for funding will not be subject to public release.

B. Marking of Proprietary Information

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

C. Award Notices

Awards are made to organizations, not to individual Principal Investigators (PIs). The USAMRMC 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 a matter of negotiation prior to award. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, 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 United States Government (31 USC 6303).
2. **An assistance agreement (grants or cooperative agreements)** is appropriate when the federal government transfers a “thing of value,” to a “state, local government,” or “other recipient,” to carry out a public purpose of support or stimulation authorized by a law of the U.S., 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. DoD staff may become directly involved in performing the research, managing the effort, and/or reviewing and providing approval before work can proceed.

After email notification of proposal/application review results through the electronic Biomedical Research Application Portal (eBRAP), and if selected for funding, a representative from the U.S. Army Medical Research Acquisition Activity (USAMRAA) will contact the business official authorized to negotiate on behalf of the PI's organization.

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

D. Inquiry Review

If a proposal/application is not recommended for funding, the organization or PI may submit an inquiry within 30 business days after the date on which the funding status notification email for that proposal/application is sent. Inquiries submitted after 30 business days will not be considered. The inquiry must specifically address a **factual or procedural error** that is believed to have occurred during review of the proposal/application. Inquiries in response to funding recommendations should be submitted to the USAMRAA Contracting or Grants Officer through the CDMRP Help Desk at help@eBRAP.org. An inquiry review panel will determine whether a factual or procedural error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. Considering the recommendation of the inquiry review panel, a final determination will be made by the USAMRAA Contracting or Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the CDMRP Help Desk at help@eBRAP.org.

E. Information Service: Applicants may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; telephone: 703-605-6000 (<http://www.ntis.gov/>) to obtain information about existing research to avoid duplication of scientific and engineering effort.

F. Freedom of Information Act Requests

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the FOIA (www.usdoj.gov/oip/index.html).

When a FOIA request asks for information contained in a successful proposal/application that has been incorporated into an award document, the applicant 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 USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the applicant will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

G. Information Release

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

The following are examples of statements that may be required. Specific required language will be included in each award.

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 Department of Defense (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 (or other sponsoring agency), through the (insert program name) under Award No. (W81XWH-15-X-XXXX). Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the DoD.”
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 Animal Care and Use Review Office (ACURO) website (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).
3. “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules. (<http://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. (<http://www.cdc.gov/biosafety>)”

Failure to comply may result in loss of funding.

H. Reporting Requirements for Awards

The government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the government will be described in each award and may include:

- Technical/Scientific:
 - Quarterly and/or annual progress reports
 - Final progress report
 - Quad charts

USAMRMC research progress reporting requirements and instructions can be found at https://mrmc-www.army.mil/index.cfm?pageid=mrmc_resources.rrpindex.

- Fiscal (SF 425 “Federal Financial Report”) (assistance agreements only):
 - Quarterly and/or annual reports
 - Final report
- Regulatory:
 - Research with Human Subjects - For DoD awards that include funding to support research with human subjects, the USAMRMC’s Human Research Protections Office (HRPO) requires submission of institutional continuing review reports and study event reports. Instructions are found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.
 - Research Involving Animals – For DoD awards that include funding to support animal studies, staff from the USAMRMC’s Animal Care and Use Review Office (ACURO) will contact the PI regarding submission requirements and deadlines. Questions related to ACURO review and approval should be directed to the ACURO central email account at usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil.

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

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 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the award.

J. Sharing of Data and Research Resources

It is the intent of the USAMRMC that data and research resources generated by USAMRMC-funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the USAMRMC. This includes all data and research resources generated during the project’s period of performance as annotated in the assistance agreement. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:

- **Unique Data**¹ are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.
- **Final Research Data**² are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
- **Research Resources**³ include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

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

By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with federal funds. The USAMRMC believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.

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

¹ Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

² Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

³ Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf

K. Transfer of Award

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

Transfer of Assistance Agreement: Transfer of an assistance agreement to a new organization (e.g., if the PI relocates to another organization) will be considered on a case-by-case basis by the USAMRAA Grants Officer and will require the PI's original organization to agree to relinquish the award. The new organization will be required to resubmit the entire application on behalf of the PI, including regulatory documentation. The transfer of an award that includes a study site/clinical trial at its location will only be approved under unusual circumstances.

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

M. Property/Equipment

Contracts: Reference FAR Part 45 and DFARs Part 245.

Assistance Agreements: Unless otherwise specified in the award, the title to equipment or other tangible property purchased with government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the organization for the government. Title to equipment or other tangible property purchased by for-profit organizations will conditionally vest in the organization subject to the requirements of the Department of Defense Grant and Agreement Regulations, Part 34.21. However, if the award is subsequently transferred to a new organization, the DoD reserves the right to require the transfer of equipment purchased with the award funds to the federal government or to an eligible third party.

N. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, subject to meeting the reporting and patent filing requirements and retained rights to the government. The federal government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Instructions in the assistance agreement concerning subject inventions must be followed. For additional information, reference:

Contracts: FAR Part 27 and DFARs Part 227.

Assistance Agreements: DoDGAR Parts 32.36 and 34.25.

O. J-1 Visa Waiver

An organization located outside of the U.S. may submit in response to the BAA. Each organization, located inside or outside of the U.S., is responsible for ensuring that the personnel associated with any proposal/application recommended for funding are able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the U.S.

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

Additional information on J-1 Visa Waivers can be located at the following Department of State website: <http://www.travel.state.gov/content/visas/english/study-exchange/exchange.html>.

APPENDIX 4

NATIONAL POLICY REQUIREMENTS

The following representations, certifications, and assurances listed in the Grants.gov application package of forms (SF424B) are applicable depending on the resultant award type. Any additional required representations, certifications, and assurances will be requested prior to award.

For regulatory requirements regarding the environment, and for use of animal and human subjects in research, refer to [Appendix 5](#).

A. Contract Awards: Representations and Certifications: The applicant must complete the representations and certifications electronically via the System for Award Management (SAM) website accessed through <https://www.acquisition.gov> or <https://www.sam.gov>. By signing and submitting the proposal, the applicant certifies that the representations and certifications currently posted electronically via SAM have been entered or updated within the last 12 months, are current, accurate, and complete, and applicable to this BAA.

B. Assistance Agreement Awards:

National policy requirements applicable to the Department of Defense (DoD) awards are listed in Appendices A and B to Part 22 of the DoD Grant and Agreement Regulations (DoDGAR) (32 CFR Subtitle A, Chapter 1, Subchapter C) (<http://www.gpo.gov/fdsys/pkg/CFR-2011-title32-vol1/xml/CFR-2011-title32-vol1-subtitleA-chapI-subchapC.xml>).

1. Certification Regarding 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 Section 1352, Title 31 of the U.S. Code and is a prerequisite for making or entering into an award over \$100,000. Complete form Standard Form (SF) LLL, "Disclosure of Lobbying Activities," if applicable, and attach to Block 18 of the SF424 (R&R) form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

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

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, and the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

- (2) If any funds other than Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

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

2. Representations (applicable to corporations only):

In accordance with DoD appropriations, applicant organizations that are corporations are required to complete the representations below and submit with each proposal/application. The form for completion is posted in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). The form should be completed and uploaded to eBRAP.

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

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

- (1) Is _____ is not _____ a Corporation ("Corporation" means any entity, including any institution of higher education, other non-profit organization, or for-profit entity that has filed articles of incorporation) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.
- (2) Is _____ is not _____ a Corporation that was convicted of a criminal violation under any Federal law within the preceding 24 months.

NOTE: If the applicant organization responds in the affirmative to either of the above representations, the organization is ineligible to receive an award unless the agency suspension and debarment official has considered suspension or debarment and determined that further action is not required to protect the Government's interests. The applicant organization therefore will be required to provide information about its tax liability and/or conviction, upon request, to the Grants Officer, to facilitate completion of the required consideration before award decisions are made.

- 3. Requirements for Federal Funding Accountability and Transparency Act Implementation (2 CFR 170): Appendix A to Part 170**, incorporated herein by reference. The full text is available on <http://www.usamraa.army.mil/>.
- 4. Financial Assistance Use of Universal Identifier and Central Contractor Registration (2 CFR 25): Appendix A to Part 25**, incorporated herein by reference. The full text is available on <http://www.usamraa.army.mil/>.
- 5. Trafficking Victims Protection Act**

Trafficking in persons.

- a. Provisions applicable to a recipient that is a private entity.
 1. You, as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not:
 - i. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
 - ii. Procure a commercial sex act during the period of time that award is in effect; or
 - iii. Use forced labor in the performance of the award or subawards under the award.
 2. We, as the Federal awarding agency, may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity:
 - i. Is determined to have violated a prohibition in paragraph a.1. of this award term; or
 - ii. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph a.1. of this award term through conduct that is either:
 - A. Associated with performance under this award; or
 - B. Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 CFR 1125.
- b. Provision applicable to a recipient other than a private entity. We, as the Federal awarding agency, may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity:
 1. Is determined to have violated an applicable prohibition in paragraph a.1. of this award term; or
 2. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1. of this award term through conduct that is either:
 - i. Associated with performance under this award;

- ii. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, “OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement),” as implemented by our agency at 2 CFR part 1125.
- c. Provision applicable to any recipient.
 - 1. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph a.1. of this award term.
 - 2. Our right to terminate unilaterally that is described in paragraph a.2. or b. of this section:
 - i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 USC 7104(g)), and
 - ii. Is in addition to all other remedies for noncompliance that are available to us under this award.
 - 3. You must include the requirements of paragraph a.1. of this award term in any subaward you make to a private entity.
- d. Definitions. For the purpose of this award term:
 - 1. “Employee” means either:
 - i. An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or
 - ii. Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.
 - 2. “Forced labor” means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.
 - 3. “Private entity” means:
 - i. Any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 CFR 175.25.
 - ii. Includes:
 - A. A non-profit organization, including any non-profit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 CFR 175.25(b).
 - B. A for-profit organization.
 - 4. “Severe forms of trafficking in persons,” “commercial sex act,” and “coercion” have the meanings given at section 103 of the TVPA, as amended (22 USC 7102).

C. Assurances for Assistance Agreements

The following list of Assurances, included herein by reference, will be included in full text as terms and conditions of each assistance agreement award, as applicable. The full text of the Assurances is available on <http://www.usamraa.army.mil/>.

- Nondiscrimination
- Campus Access for Military Recruiting and Reserve Officer Training Corps
- Research involving recombinant dna molecules
- Radioactive materials
- Officials Not to Benefit
- Preference for U.S.-Flag Air Carriers
- Cargo Preference
- Environmental Standards
- Drug-Free Workplace
- Debarment and Suspension

APPENDIX 5

REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, DA PAM 385-10, 32 CFR 651 6 Sep 2012), provisions previously requested for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, select biological agents or toxins, select chemical agent(s), or pesticides outside of an established laboratory. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Surety, Safety, and Environment will identify any need for compliance review, and documents must be submitted upon request.

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the USAMRMC and involving human subjects, human anatomical substances, human data, human cadavers, and animals are conducted in accordance with federal, DoD, Army, USAMRMC, and international regulatory requirements.

Principal Investigators (PIs) and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until and unless regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, “Use of Animals in DoD Programs,” as issued September 13, 2010, available at <http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf> and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” as issued on November 8, 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human data and/or specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI’s institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_Animalappendix. ***Allow at least 2 to 3 months for regulatory review and approval processes for animal studies.***

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

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

Research, development, test and evaluation (RDT&E), education, or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/assets/docs/orp/army-policy-for-use-of-human-cadavers_042012.pdf). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

E. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances



In addition to local Institutional Review Board (IRB) review, investigators must submit all USAMRMC-funded research protocols involving human subjects and human anatomical substances for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (<https://ebrap.org/eBRAP/public/Program.htm>). This information is a guide only; it is not intended to be a source for human subject protection regulations. Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).



ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific laws and requirements governing research involving human subjects. These laws and directives may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already-approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at https://mrmc.amedd.army.mil/assets/docs/orp/hrpo_information_for_investigators_050712.pdf. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections_hrpo.

- 1. Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.
- 2. Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.
- 3. Informed Consent Form:** The following must appear in the consent form:
 - A statement that the Department of Defense (DoD) is providing funding for the study.
 - A statement that representatives of the DoD are authorized to review research records.
 - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.
- 4. Intent to Benefit:** The requirements of Title 10 United States Code Section 980 (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.”

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 study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo 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. Note that the definition of **experimental subject** as defined in the DoDI 3216.02 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.



10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at Usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.

Research Monitor Requirement: *For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.* The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- overseeing study interventions and interactions;
- reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- shall have the responsibility for promptly reporting their observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

5. Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel as volunteers.

- **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with service-specific requirements.

A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order service members to participate in a research study.

For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.
- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

6. **Site Visits:** The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.



Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

7. **Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

D. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of “CDMRP-CDMRP Log Number” (e.g., CDMRP-BA15#####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “CDMRP-CDMRP Log Number-A, B, C, etc.” (e.g., CDMRP-BA15#####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (<http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

APPENDIX 6

ACRONYM LIST

A&R	Alteration and Renovation
ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CCR	Central Contractor Registry
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ET	Eastern Time
F&A	Facilities and Administrative
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative
HIPAA	Health Information Portability and Accountability Act
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MPEG	Moving Picture Experts Group
NCAGE	NATO Commercial and Government Entity
OMB	Office of Management and Budget
ORP	Office of Research Protections
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
SAM	System for Award Management
SOW	Statement of Work

TIFF	Tagged Image File Format
TIN	Tax Identification Number
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio