# General Application Instructions

# Fiscal Year 2013

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

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***This General Application Instructions document is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the Program 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 Program Announcement/Funding Opportunity for specific instructions.

## B. Current Funding Opportunities

To view all funding opportunities currently offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov (http://www.grants.gov/) search using the Catalog of Federal Domestic Assistance (CFDA) Number 12.420. Additional information may be found on the CDMRP website at http://cdmrp.army.mil/funding/ and on the CDMRP eReceipt System website at https://cdmrp.org/Program_Announcements_and_Forms/. To receive email notifications when CDMRP funding opportunities are released, submit a request via email to help@cdmrp.org. Email notifications of funding opportunities are sent as a courtesy and should not be used as a sole source of notification; applicants should monitor Grants.gov for official postings of funding opportunities.

## C. Receiving Emails from the CDMRP, CDMRP eReceipt System, 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 the CDMRP eReceipt System and Grants.gov and place the following domains into your safelist: army.mil, amedd.army.mil, us.army.mil, *.mail.mil, cdmrp.org, and grants.gov.

## D. Agency Contacts

1. **CDMRP Help Desk:** Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to submission of pre-applications through the CDMRP eReceipt System 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@cdmrp.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 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-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

The Principal Investigators (PIs) and organizations identified in the applications submitted through Grants.gov should be the same as those identified in the pre-applications.

***For specific instructions regarding changes to the PI or organization, refer to the Program Announcement/Funding Opportunity.***

On occasion, the CDMRP may update or change the application package in Grants.gov. The applicant must use the latest version of the application package; applications submitted with a different version of the application package may 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 specific Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package***.

***Submission of applications from U.S. federal agencies has unique requirements.*** Any applicant planning to use a third party entity to administer award funding or in collaboration should submit the application through that entity. In addition, budget restrictions apply. See Section 4: Research & Related Budget.

### A. Submission Dates and Times

All pre-application and application components must be submitted by the deadlines identified in the Program Announcement/Funding Opportunity. Material submitted after the deadlines, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet any one of the deadlines will result in application rejection.

Before starting the Grants.gov submission process, the organization must be registered as an Entity in the System for Award Management (SAM) and have received confirmation that its account is in an "**Active**" status. SAM registration may take 10 or more days to complete. Foreign entities are advised to begin the registration process 3 to 4 weeks in advance of its anticipated Grants.gov application submittal. See Appendix 3 for additional information.

***Start the submission process early, at least 72 hours before the pre-application and application submission deadlines.*** Both the CDMRP eReceipt System and Grants.gov have a number of required steps that must be completed before submissions will be

accepted. Make sure to allow adequate time for completion of all pre-application and application steps by their respective deadlines.

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

All pre-application components must be submitted through the CDMRP eReceipt System (https://cdmrp.org/) by the deadline specified in the Program Announcement/ Funding Opportunity. Remember to press the "Submit" button to finalize the pre-application; otherwise, the pre-application will remain in draft status and will not be accepted.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs.

***For specific instructions regarding content of the pre-application submission components, refer to the Program Announcement/Funding Opportunity.***

**Application Information – Tab 1:** Enter the application information as described in the CDMRP eReceipt System before continuing the pre-application.

**Application Contacts – Tab 2:** 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's contact information is required in the CDMRP eReceipt System or the pre-application will not be accepted**; however, the CDMRP does not require approval of the pre-application by the PI's organization..

**Collaborators and Conflicts of Interest (COIs) – Tab 3:** To enable the CDMRP to avoid COIs during the screening and review processes, list the names of all scientific participants in the proposed research project, including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees. Add all individuals outside of the application who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship) and choose "COI" from the drop-down list.

No member of the FY13 Integration Panel (IP) for the program to which an application is submitted may be named as being involved in the research proposed or found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and development of any supporting document. A list of the FY13 IP members for any CDMRP program may be found on that program's page on the CDMRP website (http://cdmrp.army.mil/).

To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors in applications for funding. For FY13, the peer review contractor is SRA International, Inc. The programmatic review contractor is Science Applications International Corporation

(SAIC). Applications including personnel from any of these companies will be administratively withdrawn unless plans to mitigate COIs are provided and deemed appropriate by the Government. For questions related to this topic, contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

**Required Files – Tab 4:** Upload all documents as individual PDF files. Documents should conform to the formatting guidelines outlined in Appendix 2.

At this time, the CDMRP eReceipt System is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

**Submit Pre-Application – Tab 5:** 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-application submission.

Confirm that the pre-application has been submitted by verifying that the status listed in the CDMRP eReceipt System has changed from "DRAFT" to "SUBMITTED." An ***applicant with a pre-application in draft status after the pre-application submission deadline is ineligible to submit an application.***

**Other Documents Tab:** This tab is not applicable unless other documents are specifically requested by the CDMRP in the Program Announcement/Funding Opportunity.

## C. Content and Form of Application Submission

Each application submission must include the completed Grants.gov application package of forms associated with the specific Program Announcement/Funding Opportunity in Grants.gov (http://www.grants.gov/). Refer to Appendix 3 for additional information on Grants.gov requirements.

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

***Submit applications at least 72 hours before the application submission deadline to allow time for Grants.gov validation of the application and, if necessary, resubmission as a "Changed/Corrected Application" prior to the deadline.***

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 point in time with an incompatible version of Adobe Reader.*** If multiple individuals are working on the same application package, all must use a compatible version of Adobe Reader. If an application is rejected due to use of an inappropriate Adobe Reader version, a new application package must be downloaded, completed, and submitted using a supported version of Adobe Reader.

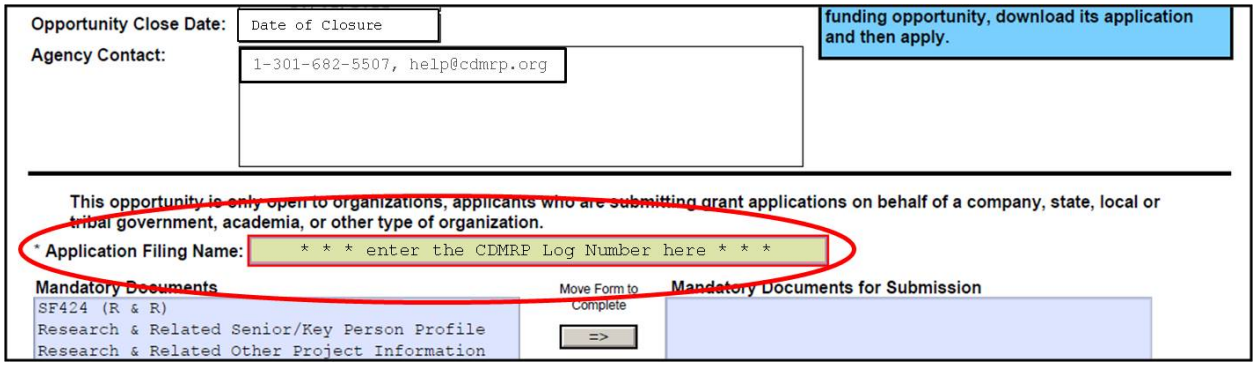
Visit the following website to verify that the version of Adobe Reader being used is compatible with Grants.gov: http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp, or download a no-cost compatible version at http://www.grants.gov/help/download_software.jsp.

### CDMRP Log Number

During the pre-application process, each submission will be assigned a unique log number by the CDMRP eReceipt System. The corresponding Grants.gov application package must be submitted using this unique CDMRP log number. Enter the CDMRP log number in one of two ways:

- **Manual Entry:** Fill in the **Application Filing Name** on the first screen of the Grant Application Package (Figure 1) using only the **CDMRP log number** (e.g., PC13####, BC13####, OC13####, NF13####, etc.) assigned during the pre-application process.

**Figure 1. Application Filing Name**




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

### The application consists of the following components:

Each attachment to the Grants.gov application forms must be an individual PDF file in accordance with the formatting guidelines listed in Appendix 2.

### 1. 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 application package must be resubmitted with the "Changed/Corrected Application" box selected.

- **Block 2 – Date Submitted.** Enter the date the application is submitted.
    - **Applicant Identifier.** Enter the submitting organization's Control Number, if applicable. This information can be obtained from the organization's Office of Sponsored Research or business unit responsible for contracting. If there is no Organization Control Number, leave this field blank.
- **Block 3 – Date Received by State.** Not applicable.
- **State Application Identifier.** Not applicable.
- **Block 4 – a. Federal Identifier Box.** This box will be populated by Grants.gov for an original application. For changed/corrected applications, enter the Grants.gov tracking number (the Federal Identifier Number assigned to the original application).
- **Block 4 – b. Agency Routing Identifier.** Not applicable.
- **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 United States, enter 44-4444444.
- **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
- **Block 8 – Type of Application.** Select "New" for all submissions.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter the same project title as used for the pre-application.
- **Block 12 – Proposed Project.** Enter the estimated start and end dates for the project. The estimated start date should be no earlier than 4 months after the period of Programmatic Review as indicated on the title page of the Program Announcement/ Funding Opportunity. The estimated end date should reflect the time needed to successfully complete the proposed project and not exceed the maximum period of performance allowed by the Program Announcement/Funding Opportunity. Actual start and end dates will be determined during negotiations if the application is recommended for funding.
- **Block 13 – Congressional District of Applicant.** If the applicant organization is outside the United States, enter 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 application. If outside the United States, select the appropriate country from the drop-down menu.
- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project. These figures should match those provided in the Research & Related Budget.

- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option "b. NO, program is not covered by E.O.12372."
- **Block 17 – Complete Certification.** Select the "I agree" box to provide the required certifications and assurances**.**
- **Block 18 – SFLLL 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.

**2. Attachments Form**

***For all attachments, ensure that the file names are consistent with the guidance below. Grants.gov will reject attachments with incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. Grants.gov does not validate for the presence of attachments.***

***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 Program Announcement/Funding Opportunity.***

All documents that require signatures must be signed. Both electronic and hand signatures will be accepted.

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 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. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

**Attachment 2: Supporting Documentation:** Combine and attach as a **single PDF file named "Support.pdf."** Include only supporting documentation as indicated in the Program Announcement/Funding Opportunity. Submitting material that was not requested may be viewed as an attempt to gain an unfair competitive advantage; such material will be removed or the application may be administratively withdrawn. ***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. Any additional material viewed as an extension of the Project Narrative will be removed or result in administrative withdrawal of the application.***

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

***For a list and descriptions of required supporting documents, refer to the Program Announcement/Funding Opportunity.***

**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. Proprietary or confidential information should ***not*** be included. ***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: Lay Abstract: Named "LayAbs.pdf."** Abstracts of all funded research projects will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included. ***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 5: Statement of Work (SOW): Named "SOW.pdf."** The SOW is an outline of specific aims defined within the proposed research project that establishes the PI's performance expectations and timeline during the performance period of the award.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined step-by-step as they relate to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, the SOW should also:

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); animal or human use to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or anatomical samples projected or required for each task. As applicable, estimated times to complete each task should include time for local and Department of Defense (DoD) regulatory review and approval, as shown below. Refer to Appendix 5 for additional information regarding regulatory review.
    - For studies involving human subjects, allow at least 2 months for regulatory review and approval processes to include local Institutional Review Board (IRB) and DoD Human Research Protection Office (HRPO).
    - For animal studies, allow 2 months for regulatory review and approval processes to include local Institutional Animal Care and Use Committee (IACUC) and DoD Animal Care and Use Review Office (ACURO).
- Identify methods.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- If applicable, indicate time required for submission and/or approval of documents (e.g., Investigational New Drug [IND] and Investigational Device Exemption [IDE]) to the U.S. Food and Drug Administration or appropriate Government agency.

***For any specific instructions regarding the SOW content, refer to the Program Announcement/Funding Opportunity.***

**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 specific examples are available on the CDMRP eReceipt System "Program Announcement and Forms" web page (https://cdmrp.org/Program_Announcements_and_Forms/). The SOW must be in PDF format prior to attaching.

Task 1. Brief descriptive overview of this task (timeframe, e.g., months 1-18):
1a. Description of subtask 1a (timeframe, e.g., months 1-4).
1b. Description of subtask 1b (timeframe, e.g., months 6-12).
1c. Description of subtask 1c (timeframe, e.g., months 1-18).

Task 2. Brief descriptive overview of this task (timeframe, e.g., months 4-36):
2a. Description of subtask 2a (timeframe, e.g., months 4-12).
2b. Description of subtask 2b (timeframe, e.g., months 13-25).
2c. Description of subtask 2c (timeframe, e.g., months 25-30).
2d. Description of subtask 2d (timeframe, e.g., months 25-36).

The Government reserves the right to request a revised SOW format and/or additional information.

**Attachments 6-15: Additional Documents (as applicable):** Attach each as a separate PDF file, named as indicated in the Program Announcement/Funding Opportunity (e.g., "Impact.pdf," "Innovation.pdf," "Training.pdf," "Transition.pdf," etc.).

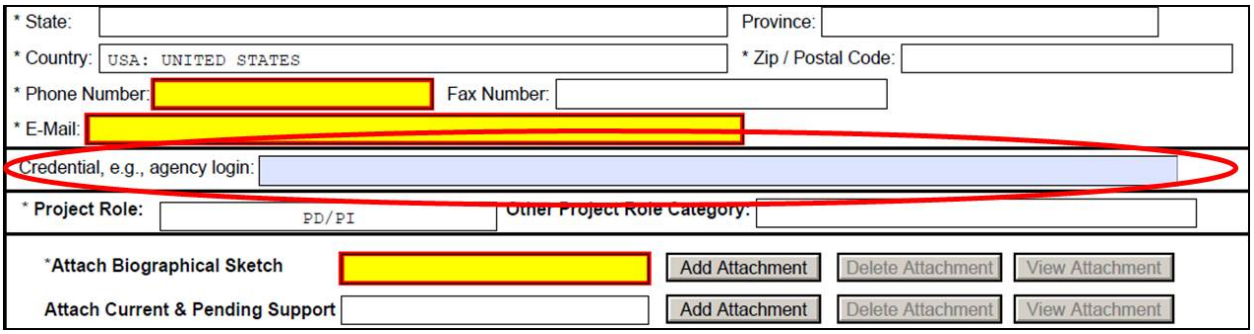
***For specific instructions regarding content, titles, and page limits for the Additional Documents, refer to the Program Announcement/Funding Opportunity.***

## 3. 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 User Name provided from the CDMRP eReceipt System into the data field labeled "Credential, e.g., agency login" (Figure 2).

**Figure 2. Credential, e.g., agency login.**




**Biographical Sketch Suggested Format:** The suggested biographical sketch format is available in a Microsoft Word document on the "Program Announcement and Forms" web page (https://cdmrp.org/Program_Announcements_and_Forms/) in the CDMRP eReceipt System. 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 Current/Pending Support:** This file must be titled "Support_LastName.pdf," where "LastName" is the last name of the PI.

   ***For all current and pending research support, include*** the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting/ 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 current and pending research projects. Clearly state if there is no overlap.

   If there is no current or pending support, enter "None." An updated current and pending support document will be required during award negotiations.

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 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 Current/Pending Support" listed above.

**4. Research & Related Budget**

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must accompany each application. ***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 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. Use the Research & Related Budget form that is available for download on the Grant Application Package page for the Program Announcement/Funding Opportunity in Grants.gov.

***For limits on funding amounts, types of costs, and period of performance, refer to the Program Announcement/Funding Opportunity. Proposed costs that exceed the maximum allowed or of types not allowed may result in administrative withdrawal of the pre-application or application.***

***For all federal agencies or organizations collaborating with federal agencies applying to this Program Announcement/Funding Opportunity, special restrictions apply to the budget and are described below.***

**Budget Regulations and Restrictions:** The following must be utilized in developing the budget:

- **Maximum Obligation:** Awards will not be modified to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **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 3210.6-R
  - 2 CFR 220, "Cost Principles for Educational Institutions (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"

- **Cost of Preparing Applications:** The cost of preparing applications in response to a CDMRP Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant award. However, the cost of preparing applications may be an allowable expense to the indirect/facilities and administrative cost as specified in the organization's applicable cost principles.
- **Currency:** All costs must be entered in U.S. dollars. Recipients performing research outside of the United States 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 Data Universal Numbering System (DUNS) number, Budget Type, Name of Organization, and anticipated start and end dates. ***Ensure that the DUNS number is entered accurately or Grants.gov may reject the application.***

**For federal agencies or organizations collaborating with federal agencies:** Applications from federal agencies or from organizations collaborating with federal agencies must include in their budget justifications (detailed instructions below) a **Federal Agency Financial Plan** delineating 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, such as through agreements with foundations, non-federal organizations, universities, or through other means. It should be noted, however, that it is contrary to policy to allow for any recipient to reimburse a federal agency for any costs except under very limited circumstances allowed by USAMRMC policy.

**Section A: Senior/Key Person**

- **Prefix; First, Middle and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under section F.3.
- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
- **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 and therefore these salaries must not be included in the requested budget.***
- **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.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.

**Section B: Other Personnel:**

- **Number of Personnel:** For each project role category indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
- **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.
- **Requested Salary:** Enter the amount of salary requested for this budget period. ***For most federal organizations applying, funding cannot be applied toward federal salaries and therefore these salaries must not be included in the requested budget.***

- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. If the application is recommended for funding, the organization will be required to provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement or other policy document).
- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

**Section C: Equipment Description:** Equipment is 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:

- Special test equipment to be fabricated for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- 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:

- Costs to attend one or more scientific/technical meetings per year: Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity. 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; costs may not exceed the allowable amount.
- Costs for travel associated with the execution of the proposed work (if applicable): Reasonable costs for travel between collaborating organizations should be included and are not subject to the yearly cost limitation on travel to scientific/technical meetings. International travel may be requested but must be well justified and is subject to approval; costs may not exceed the allowable amount.
- Costs to attend required meetings (if applicable): Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity, if a limit is provided. Include the meeting name if identified in the Program Announcement/Funding Opportunity (e.g., Era of Hope, IMPaCT) and a statement in the budget justification confirming that the PI will attend the required meeting. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs of DoD employees that are approved for this project will be paid by the Government. No funds will be paid by the recipient to either the DoD or individual DoD employees to cover such costs.

**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.

5. **Subaward/Consortium/Contractual Costs:** Include the total funds 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.

***All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award. The total direct costs of the primary award, including the direct and indirect subaward costs, cannot exceed the maximum allowed as specified in the Program Announcement/Funding Opportunity.***

6. **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.

7. **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project

and are a minor portion of the overall budget. 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.

8. **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 Rate Agreement or other policy document) via the CDMRP eReceipt System (https://cdmrp.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.

***Organizations must provide sufficient detail and justification so the Government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.***

**5. 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.

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

Complete a separate detailed Research & Related Budget 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.

***All direct and indirect costs of any subaward must be included in the total direct costs of the primary award. The total direct costs of the primary award, including the direct and indirect subaward costs, cannot exceed the maximum allowed as specified in the Program Announcement/Funding Opportunity.***

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

## APPENDIX 1

## QUALIFICATION AND ELIGIBILITY INFORMATION

### A. Recipient Qualification

To protect the public interest, the federal Government ensures the integrity of federal programs by only conducting business with qualified recipients. To be qualified, a potential recipient must at least (1) have a satisfactory record of executing programs or activities under federal assistance or procurement awards, if it is a prior recipient of such awards; (2) have a satisfactory record of integrity and business ethics; and (3) meet the standards of DOD 3210.6-R, Part 22.415. The US Army Medical Research and Materiel Command (USAMRMC) 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 Program Announcement/Funding Opportunity 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 United States: 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.

## APPENDIX 2

## FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ 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, 10 pitch.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF 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:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Program Announcement/Funding Opportunity (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.

## APPENDIX 3

## GRANTS.GOV REQUIREMENTS

Prior to submission of an application through Grants.gov, a pre-application must be submitted to the CDMRP eReceipt System at https://cdmrp.org for all Congressionally Directed Medical Research Programs (CDMRP) Program Announcements/Funding Opportunities. This is a required step. Following pre-application submission to the CDMRP eReceipt System, applications must be submitted through the federal Government's single entry portal, Grants.gov.

***Organizations must register in Grants.gov to submit applications through the Grants.gov portal. The registration process may take several weeks, so organizations should register as soon as possible. Organizations must also register in the System for Award Management (SAM). Allow a minimum of 10 days to complete this registration. Foreign entities are advised to begin the registration process 3 to 4 weeks in advance of its anticipated Grants.gov application submittal.***

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 SAM. Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp.

***Effective July 30, 2012, the Central Contractor Registry (CCR), Federal Agency Registration (FedReg), On-line Representations and Certifications Application (ORCA) and Excluded Parties List System (EPLS) legacy systems have been migrated to the General Services Administration's (GSA) SAM. If you have previously entered your organization in CCR, ORCA, or FedReg, all of your organization's information should have been supplied to the Entity Management functional area of SAM. Each organization should check to make certain this has occurred and that information is accurate. Additional information and step-by-step registration directions are detailed in the SAM User Guide and other GSA training materials in the Help area at www.sam.gov.***

**The following actions are required as part of the registration process:**

**A. Data Universal Numbering System (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 United States can request and register for a DUNS number online via web registration.

**B. System for Award Management (SAM) Registry:** The applicant organization must be registered as an Entity with the SAM (http://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 www.sam.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. If you have the necessary information, online registration will take about 1 hour to complete, depending upon the size and complexity of your organization. Allow a minimum of 10 business days to complete the entire SAM registration. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service.

***Applications will be rejected by Grants.gov if the organization's Entity registration in SAM is not current and accurate.***

**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 have a NATO CAGE Code (NCAGE) assigned. 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.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 Organization 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 organization 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.

## APPENDIX 4

## ADMINISTRATIVE INFORMATION

### A. Defense Health Program Authority

The Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)] exercises authority, direction, and control over Defense Health Program Research, Development, Test and Evaluation activities including certain Congressional Special Interest (CSI) appropriations. The OASD(HA) established an Interagency Support Agreement with the U.S. Army Medical Research and Materiel Command (USAMRMC) to manage the execution of these CSI appropriations. Within USAMRMC, the Congressionally Directed Medical Research Programs (CDMRP) is responsible for the day-to-day execution functions of these CSI appropriations, and performs activities such as developing solicitations for applications for funding, conducting peer and programmatic review of applications, and overall program management. Other USAMRMC organizations are responsible for award of assistance agreements, funds management, and a variety of follow-on program management, legal and regulatory review, and compliance actions.

### B. Disclosure of Proprietary Information Included in an Application

Proprietary information submitted in an application may be disclosed outside the Government for the sole purpose of technical evaluation. Evaluators must agree that proprietary information in the application will be used for evaluation purposes only and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act.

### C. Award Negotiations

Extramural research programs are implemented predominantly through the award of assistance agreements that are made to an organization, not to the individual Principal Investigator(s) (PI[s]). 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. The award start date will be determined during the negotiation process.

Only an appointed USAMRAA 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. Any pre-award costs associated with a research effort are made at an organization's own risk. The incurring of pre-award costs by an organization does not impose any obligation on the Government in the absence of appropriations, if an award is not made, or if an award is made for a lesser amount than an organization expected.

### D. Administrative and National Policy

The award provisions of Appendix B to Part 22 of the DODGAR 3210.6-R apply to all assistance agreements (http://www.dtic.mil/whs/directives/corres/pdf/321006r22apbp.pdf). Refer to this General Applications Instructions, Appendix 5, for further regulatory requirements.

Award recipients will also be required to complete "Certifications and Assurances for Assistance Agreements" http://www.usamraa.army.mil/pages/regulatory/certs2007.pdf) prior to award.

### E. 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: quarterly, mid-term, annual, and final research progress reports; fiscal reports; non-exempt human studies reports; and animal use reports. USAMRMC research progress reporting requirements and instructions can be found at https://mrmc-www.army.mil/index.cfm?pageid=mrmc_resources.rrpindex. Forms for fiscal and animal use reports can be found at http://www.usamraa.army.mil/index.cfm?ID=12&Type=3#Forms. The Government may request additional reports, which will be identified in the award.

### F. Organization or PI Changes after Award Initiation

Unless restricted by the specific Program Announcement/Funding Opportunity, a change in organizational affiliation will be considered 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 packet to USAMRAA on behalf of the PI. The application packet must include regulatory documentation to be approved for the new organization. Unless otherwise restricted, changes in PI will be made at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

### G. Equipment

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 DODGAR 3210.6-R, Part 34.21. However, if the award is subsequently transferred to a new organization, the Department of Defense (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.

### H. Inquiry Review

If an 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 application is sent. The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the application. Inquiries in response to funding recommendations should be submitted to the USAMRAA Grants Officer through the CDMRP Help Desk at help@cdmrp.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 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@cdmrp.org.

### I. J-1 Visa Waiver

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

### J. 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, but the U.S. 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.

### K. Sharing of Data and Research Resources

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

For the purposes of the CDMRP, expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the CDMRP. 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.

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[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

- **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 CDMRP-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 CDMRP believes that such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.

***For additional information on CDMRP expectations for data-sharing, refer to the document titled "Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources," available on the CDMRP eReceipt System under Reference Material at https://cdmrp.org/Program_Announcements_and_Forms/.***

[3] Adapted from http://ott.od.nih.gov/policy/rt_guide_final.html

## APPENDIX 5

## REGULATORY REQUIREMENTS

Principal Investigators (PIs) and applicant organizations may not commence performance of research involving human subjects, human anatomical substances, human cadavers, and/or human data or laboratory animals, or expend funding on such effort, until and unless applicable regulatory documents are reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (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 https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations 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 and DoDI 3216.01, "Use of Animals in DoD Programs," as issued September 13, 2010 and available at http://www.dtic.mil/whs/directives/corres/pdf/321601p.pdf.

Studies involving animals and non-exempt research involving human subjects (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances) must be approved through a regulatory review process by the PI's local Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) and by the USAMRMC Office of Research Protections (ORP). 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. ***Research involving human subjects that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI's institution as well as the ORP at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

Concurrent with the U.S. Army Medical Research Acquisition Activity negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form to be submitted upon request.

### A. Certificate of Environmental Compliance

The Certificate of Environmental Compliance will be requested prior to award negotiations. If multiple research sites/organizations are included in the application, then a Certificate of Environmental Compliance for each site will also be requested. The Certificate of Environmental Compliance can be downloaded from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/.

## B. Safety Program Documents

The Principal Investigator Safety Program Assurance form will be requested prior to award negotiations. If multiple research sites/organizations are included in the application, then a Safety Program Assurance form for each site will also be requested.

A Facility Safety Plan will be requested from each research site/organization funded by the award. Specific requirements for the Facility Safety Plan can be found at https://mrmc.amedd.army.mil/assets/docs/sse/SafetyAppendix093008.pdf. A Facility Safety Plan from a research site/organization may have been received previously and approved by the USAMRMC. A list of organizations that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/assets/docs/SSE/Facility_Safety_Plan_Approved_Institutions.pdf.

## 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 (these documents should not be submitted with the application). 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 2 to 3 months for regulatory review and approval processes for animal studies.

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

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

Research, development, testing 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/index.cfm?pageid=research_ protections.overview). The USAMRMC ORP is the Action Office (Usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Approval must be obtained from the Head of the Army organization that is supporting/funding the activity involving cadavers as described in the policy. For certain activities involving cadavers, approval must also be obtained from ORP. 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.

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

***In addition to local IRB review, all USAMRMC-funded research involving human subjects and human anatomical substances must receive a USAMRMC Headquarters-***

***level Administrative Review and be approved 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 CDMRP eReceipt System website (https://cdmrp.org/Program_Announcements_and_Forms/). 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 USAMRMC 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-specific 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 directives 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/index.cfm?pageid=research_protections.hrpo. 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 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 U. S. Army Medical Research and Materiel Command 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 facilities or 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 random 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.

## F. 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-PC13####). 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-PC13####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see http://prsinfo.clinicaltrials.gov/, click on "Data Element Definitions") are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

## APPENDIX 6

## ACRONYM LIST

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|---|---|
| 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 |
| CSI | Congressional Special Interest |
| 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 |
| IP | Integration Panel |
| IRB | Institutional Review Board |
| JPEG | Joint Photographic Experts Group |
| M | Million |
| MB | Megabyte |
| MPEG | Moving Picture Experts Group |
| MTF | Medical Treatment Facility |
| NCAGE | NATO Commercial and Government Entity |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| OMB | Office of Management and Budget |
| ORP | Office of Research Protections |
| PDF | Portable Document Format |

| | |
|---|---|
| PI | Principal Investigator |
| POC | Point of Contact |
| SAIC | Science Applications International Corporation |
| 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 |