General Application Instructions

Fiscal Year 2010

Department of Defense Congressionally Directed Medical Research Programs

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I. HELPFUL INFORMATION

A. Tips for Success

Helpful hints are marked by this symbol and have been placed throughout this document.

Refers to the Program Announcement/Funding Opportunity for specific instructions.

B. Funding Opportunities

To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov (http://www.grants.gov/) basic search using the CFDA Number 12.420. Additional information may be found on the CDMRP website at http://cdmrp.army.mil/funding/default and on the CDMRP eReceipt system website at https://cdmrp.org/Program_Announcements_and_Forms/.

C. Receiving Emails from the CDMRP, CDMRP eReceipt System, and Grants.gov

To ensure that all email correspondence is delivered correctly and is not treated as spam by email programs, please place the following domains into the safelist/whitelist: army.mil, amedd.army.mil, cdmrp.org, and grants.gov.

D. Contacts

1. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. Eastern time (ET). Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Email: cdmrp.pa@amedd.army.mil

2. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application or other documents through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507

Email: help@cdmrp.org

3. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance about Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

II. SUBMISSION PROCESS

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/). 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 shall result in application rejection.

Start the submission process early! 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.

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

The Principal Investigators (PIs) and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. Refer to the Program Announcement/Funding Opportunity for specific instructions regarding changes to the PI or organization.

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 Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

A. Step 1 – 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; otherwise, the pre-application will remain in draft status and will not be accepted.

Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the pre-application components.

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

Proposal Information - Tab 1: Enter the proposal information as described in the CDMRP eReceipt system before continuing the pre-application.

Proposal Contacts - Tab 2: Enter contact information for the PI and Contract Representative (CR). The CR is the organization's business official responsible for sponsored program administration (or equivalent). This is the individual listed as the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 form. Although CR contact information is required, the CDMRP does not require approval of the pre-application by the PI's organization.

Collaborators and Conflicts of Interest (COI) - Tab 3: To avoid COI 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 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.

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

Submit Pre-application - Tab 5: Press the "Submit" button under the "Submit Pre-application" tab to complete the pre-application submission.

The submit button must be pressed for a pre-application to be complete.

Other Documents Tab: Not applicable unless specifically requested by the CDMRP.

B. Step 2 – Application Submission

Each application submission must include the completed Grants.gov application package of forms and attachments 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.

Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the application components.

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, they must all 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.

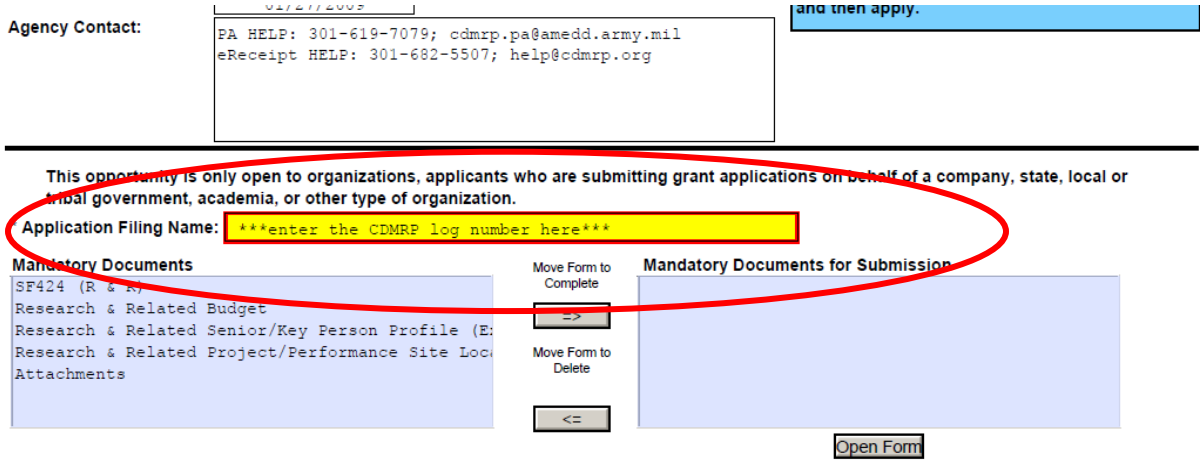
Visit the following website to verify that the version Adobe Reader being used is compatible with Grants.gov: http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp, or download a no-cost compatible version at http://www.grants.gov/help/download_software.jsp.

CDMRP Log Number

During the pre-application process, each PI will be assigned a unique and separate log number by the CDMRP eReceipt system that is specific to his/her application. Each PI must submit his/her grants.gov application package using this unique CDMRP log number. Enter the CDMRP log number in one of the two following 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., PC10####, BC10####, OC10####, NF10####, 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 CDMRP cannot make allowances/exceptions to its policies for submission problems encountered through using system-to-system interfaces with Grants.gov.

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:

- **Applicant Identifier.** Enter the submitting organization's Control Number.
- **State Application Identifier.** Not applicable.
- **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 3 – Date Received by State.** Not applicable.
- **Block 4 – Federal Identifier Box.** Leave blank for an original application. For changed/corrected applications, enter the Grant ID Number assigned to the original application.
- **Block 5 – Applicant Information.** Enter the information for the applicant organization. The "Person to be contacted on matters involving this application" is the Contract Representative or 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 a brief descriptive title of the project.
- **Block 12 – Proposed Project.** Enter 30 September 2011; the actual start date 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 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 this application. If outside the U.S., select the appropriate country from the dropdown menu.

- **Block 15 – Estimated Project Funding**. Enter the total funds (direct + indirect costs) requested for the entire performance period of the project.
- **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 31 U.S.C. 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

Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content and page limits of the Project Narrative, Supporting Documentation, and all other attachments to this Grants.gov form. 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 is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

Attachment 2: Supporting Documentation: Combine and attach as a **single PDF file named "Support.pdf."** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage, and such material will be removed. ***The Supporting Documentation attachment is not intended for additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, or cartoons that should be included in the Project Narrative.***

Refer to the Program Announcement/Funding Opportunity for a list and descriptions of required supporting documents.

Attachment 3: Technical Abstract: Named "TechAbs.pdf." Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included. ***Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.***

Attachment 4: Public Abstract: Named "PublicAbs.pdf." Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included. ***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 tasks associated with the proposed research project that establishes the PI's performance expectations and timeline during the period of performance of the award.

The SOW should include the milestones, major goals, or objectives of the proposed research/services; it should also include a list of tasks, each followed by a series of relatively short statements that outline subtasks step-by-step as they relate to the proposed specific aims, and to the period of performance. The SOW should only describe work for which funding is being requested by this application and, as applicable, the SOW should also:

- Indicate the number of research subjects (animal or human) and/or anatomical samples projected or required for each task.
    - Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.
    - Allow up to 4 months for regulatory review and approval processes for animal studies.
- Identify cell lines to be used.
- Indicate time required for submission and/or approval of applicable documents (e.g., Investigational New Drug [IND] and Investigational Device Exemption [IDE]) to the Food and Drug Administration (FDA) or appropriate government agency.
- Include the following information for each study site/subaward site: collaborator, consultant, and/or subawardee name; organization; organization address; and animal or human use at this site.

Suggested SOW format: There is no limit to the number of tasks and subtasks that are described within the SOW page limit.

Task 1. Brief overview description 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 overview description 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.

Attachment 6: Detailed Budget and Justification: Single PDF file, named "Budget.pdf." An estimate of the total research project cost, with a breakdown by category and year, must accompany each application. Provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.

Include a detailed budget and budget justification. Use the Detailed Budget and Justification form that is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity in Grants.gov.

Refer to the Program Announcement/Funding Opportunity for limits on funding and period of performance.

a. Budget Regulations: The following must be adhered to regarding budget calculations:

- **Maximum Obligation:** The USAMRMC does not modify awards to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the regulations and principles:
  - **Commercial Organizations:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 231, Contract Cost Principles and Procedures (http://farsite.hill.af.mil).
  - **Educational Institutions:** 2 Code of Federal Regulations (CFR) Part 220 Cost Principles for Educational Institutions (http://www.gpoaccess.gov/cfr/index.html).
  - **Nonprofit Organizations:** 2 CFR Part 230, Cost Principles for Nonprofit Organizations (http://www.gpoaccess.gov/cfr/index.html). OMB Circular A-133, Audits of States, Local Governments, and Nonprofit Organizations (http://www.whitehouse.gov/OMB/circulars).
  - **State, Local, and Tribal Governments:** 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (http://www.gpoaccess.gov/cfr/index.html).

- **Cost of Preparing Applications:** The cost of preparing applications in response to this Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and 2 CFR Parts 220 and 230.
- **Currency:** All costs must be entered in US dollars. Recipients performing research outside of the US should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.
- ***A profit or fixed fee is not allowable on awards or on subawards***.

b. Budget Instructions: Complete the Detailed Budget and Justification form. Begin by entering the PI name, CDMRP Log number, and period of performance fields at the top of page F-1 of the Detailed Budget and Justification form. Following the guidelines below, enter the required information under "Detailed Budget for Year One" on pages F-1 (Senior/Key Person and Other Personnel) and F-2 (Other Direct Costs). On page F-3, fill in the appropriate total amounts for each budget category for each additional year (or partial year) of support requested under "Budget for Entire Proposed Period of Performance." Itemize all budget categories for the additional years and clearly justify each budget item for the entire period of performance in the Justification section on page F-4.

Submit a Detailed Budget and Justification that covers the entire period of performance (not just the first year).

Senior/Key Person and Other Personnel: Base labor costs upon actual labor rates or salaries. Personnel cost estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period of performance. Identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification.

- **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff.
- **Role on Project:** Identify the role of each participant listed. Describe his/her specific functions in the budget justification.
- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.
- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. Costs for all sponsors must be treated consistently by the applicant organization. Provide documentation to support the fringe benefits.
- **Totals:** Calculated automatically from the data provided.

Other Direct Costs: Itemize and clearly justify all additional direct costs as components of the budget categories listed below. Enter the itemized budget information for the first year on page F-2.

- **Major Equipment:** It is Department of Defense policy that all commercial and nonprofit recipients provide the general office and laboratory equipment needed to support the proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements will be separately negotiated.

  Provide an itemized list of proposed permanent equipment, showing the cost of each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. The budget justification for each item of permanent equipment must include:

  - Vendor Quote: Show name of vendors and number of quotes received, and justification if intended award is to other than the lowest bidder. As this is a competitive process, multiple quotes should be obtained, considered, and provided.
  - Historical Cost: Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
  - Estimate: Include rationale for estimate and reasons for not soliciting current quotes.
  - Special test equipment to be fabricated by the contractor 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.
- Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

- **Travel Costs:** Travel outside the United States, including between foreign countries, requires prior approval from the Grants Officer 30 days before travel, unless identified in the application that is part of the award.

  Travel costs may include:

  - Attendance of at least one scientific/technical meeting per year. Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity.
  - 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 meetings.
  - Attendance at CDMRP-required meetings (if applicable). Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity.

- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal, and proposed vendor. If human cell lines are to be purchased, state the source, cost, and description.
- **Consultant Costs:** 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.
- **Subaward/Consortium/Contractual Costs:** Include the total funds requested for (1) all subaward/consortium organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.

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

Total Direct Costs: Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.

Total Indirect Costs: Indirect costs may include Facilities and Administrative [F&A] Costs, overhead, General and Administrative [G&A], and other. The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

If negotiated forecast rates do not exist, provide sufficient detail in the budget justification section regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or CFR provisions. Commercial organizations can also visit www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established. As a minimum, budget justification for indirect costs should identify: (1) All individual cost elements included in each forecast rate; (2) the basis used to prorate indirect expenses to cost pools, if any; (3) how each rate was calculated; and (4) the distribution basis of each developed rate.

Total Costs: This section is calculated automatically from the data provided.

c. Budget Justification: Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section (page F-4) of the Detailed Budget and Justification form. Itemize direct costs within each budget category for additional years of support requested beyond year one. ***Organizations must provide sufficient detail and justification so the Government can determine the proposed costs are reasonable for the proposed research effort. Provide a copy of your purchasing policy, which clearly sets forth competition requirements for your organization for the purchase of items and services.***

d. Federal Agency Financial Plan (if applicable): Provide a detailed Federal Agency Financial Plan, if applicable, after the end of the budget justification in the Detailed Budget and Justification form. Applications from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2011, 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, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

1) The Recipient can show that such funds will not originate from the USAMRMC award, or
2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or
3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

Attachment 7: Subaward Detailed Budget and Justification (if applicable): Combine and attach as a single PDF file, named "SubBudgets.pdf." Submit a detailed budget and justification for each subaward (subgrant or subcontract). Use the Detailed Budget and Justification form that is available for download on the Full Announcement page for the Program Announcement/Funding Opportunity in Grants.gov. Use the instructions above for Attachment 6: Detailed Budget and Justification, to complete each subaward budget and budget justification. All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

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 the proposed costs are reasonable for the proposed research effort. The following information must be provided on subawards:

- Identification of the type of subaward to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subrecipient, if known, and an explanation of why and how the subcontractor or subrecipient was selected or will be selected;

- Whether the subaward will be competitive; if noncompetitive, rationale to justify the absence of competition;
- The applicant's cost or price analysis for the subaward that supports the reasonableness of the proposed cost or price.

Attachments 8-15: Required Statements (as applicable): Attach each as a separate PDF file, named according to the title of the statement (e.g., "Impact Statement.pdf," "Innovation Statement.pdf," "Military Relevance Statement.pdf," etc.).

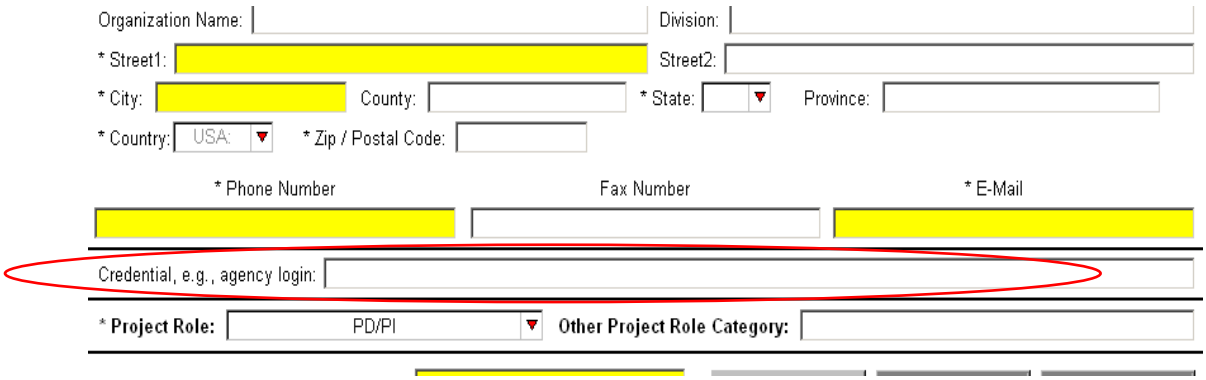
Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content and page limits for the Required Statements.

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

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

In the **"**PROFILE – Project Director/Principal Investigator" section of this form, 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.



a. PI Biographical Sketch: Form with suggested format is available for download on the Full Announcement page for the Program Announcement/Funding Opportunity in Grants.gov. Name the PDF file "Biosketch_LastName.pdf" where "LastName" is the name of the PI.

b. PI Current/Pending Support: This file must be named "Support_LastName.pdf" where "LastName" is the last name of the PI.

Applications submitted under this Program Announcement/Funding Opportunity should not duplicate other funded research projects.

For all existing and pending research projects, 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.

Identify where the proposed project overlaps with other current and pending research projects. If no current support exists, enter "None." Updated current and pending support will be required during award negotiations.

c. Key Personnel Biographical Sketches: Form with suggested format is available for download on the Full Announcement page for the Program Announcement/Funding Opportunity in Grants.gov. Each biographical sketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the appropriate individual.

d. Key Personnel Current/Pending Support: Current/Pending Support for each individual must be submitted. Name each file "Support_LastName.pdf" where "LastName" is the last name for the individual. Refer to content requirements under "PI Current/Pending Support" listed above.

3. 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 additional sites as necessary using the "Next Site" button.

APPENDIX 1

ELIGIBILITY INFORMATION

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The US Army Medical Research and Materiel Command (USAMRMC) uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] 25.110.)

A. 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.

B. Eligible Organizations: The USAMRMC makes awards to organizations. Eligible organizations include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies.

C. Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

APPENDIX 2

FORMATTING GUIDELINES

All pre-application and application documents should be clear and legible and 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 or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** Must be 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 containing 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. Links to publications referenced in the application are encouraged.
- **Language:** English.
- **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

A. Grants Policy

In compliance with P.L. 106-107, the United States Army Medical and Materiel Command requires applications submitted in response to a Program Announcement/Funding Opportunity to be submitted through the Federal Government's single entry portal Grants.gov. In addition to application submission through Grants.gov, all CDMRP Program Announcements/Funding Opportunities also require pre-application submission to the CDMRP eReceipt system at https://cdmrp.org.

B. Grants.gov Requirements

Organizations must register in Grants.gov in order to submit applications through the Grants.gov portal. The registration process can take several weeks, so please register as soon as possible.

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 Number System (DUNS) number or registration in the Central Contractor Registry (CCR). Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp. The following actions are required as part of the registration process.

1. Applicant Organization Must Have a Data Universal Number System (DUNS) Number: An organization will need 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 online via web registration (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.

2. Applicant Organization must be registered with the Central Contractor Registry (CCR): An organization must be registered with CCR (http://www.ccr.gov) before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates organization information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer.

As CCR registrations have an expiration date, authorized business officials should verify the status of their organization's CCR registration well in advance of the application submission deadline.

Non-US organizations must obtain a CAGE code prior to registering with the CCR. A CAGE code can be obtained by calling 269-961-7766 or online at http://www.dlis.dla.mil/Forms/Form_AC135.asp.

3. Authorized Organization Representative (AOR) must be registered with Grants.gov: Individual PIs do not register with Grants.gov; the Authorized Organizational Representative (AOR) is required to register. An individual may serve as both the e-business point of contact 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 organization's E-Business point of contact (POC), identified during CCR registration, must authorize an AOR.

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-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

APPENDIX 4

ADMINISTRATIVE INFORMATION

A. Award Negotiation

Extramural research programs are implemented predominantly through the award of assistance agreements that are made to the organization not the individual Principal Investigator(s) (PI[s]). A representative from the US Army Medical Research Acquisition Activity (USAMRAA) will contact the business official authorized to negotiate at the PI's organization. The award start date will be determined during the negotiation process.

Only an appointed USAMRAA Contracting/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 preaward costs associated with a research effort are made at an organization's own risk. The incurring of preaward 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.

B. 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 assistance agreement and may include: quarterly, annual, and final research progress reports; fiscal reports; non-exempt human studies reports; and animal use reports. US Army Medical Research and Materiel Command (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 reserves the right to request additional reports.

Failure to submit required reports by the established due date may result in a delay or termination of award funding.

C. Change in Organization or PI After Award

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

D. 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. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the application will only be used for evaluation purposes and will not be further disclosed or used. All applications may be subject to public release under the Freedom of Information Act; applications that are not selected for funding are not subject to public release.

E. Inquiry Review

PIs may submit an inquiry to the USAMRAA in response to funding decisions. The inquiry must specifically address a factual or procedural error that is thought to have occurred during review of the application. Inquiries should be submitted through the CDMRP Program Announcement Help Desk at cdmrp.pa@amedd.army.mil. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Contracting/Grants Officers constitute an Inquiry Review Panel. Each inquiry is reviewed to determine whether factual or procedural errors in either peer or programmatic review have occurred and, if so, what action should be taken.

F. J-1 Visa Waiver

It is the responsibility of the organization to ensure that the research staff is 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.

G. Contracted Fundamental Research

Any awards under this Program Announcement/Funding Opportunity 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), meets 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 contract or grant.

H. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), title to inventions and patents resulting from Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. Instructions in the assistance agreement concerning license agreements and patents must be followed.

I. Sharing of Data and Research Resources

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

Policies with respect to the sharing of data and research resources vary across organizations and countries. Investigators should familiarize themselves with their organization's policies governing the sharing of data and research resources, as well as the policies of the host countries and/or organizations in which they plan to conduct research.

For the purposes of CDMRP, the sharing of data and research resources applies to:

- Unique and/or final research data and unique research resources.
    - **Unique Data** is defined as data that cannot be readily replicated. Examples of this are large surveys that are too expensive to replicate; studies of unique populations, such as centenarians; studies conducted at unique times, such as a natural disaster; studies of rare phenomena, such as rare diseases.
    - **Final research data** is defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. This does not mean summary statistics or tables; rather, it means 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** include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment, and machines.
- Basic research, clinical studies, surveys, and other types of research supported by CDMRP. This applies to research that involves human subjects, and laboratory research that does not involve human subjects. It is especially important to **s**hare unique data and research resources that cannot be readily replicated.
- All data and research resources generated during the proposed project period through grants, cooperative agreements, or contracts.

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.

APPENDIX 5

INSTRUCTIONS FOR REGULATORY REQUIREMENTS

Principal Investigators (PIs) may not use, employ, or subcontract for the use of any human subjects, including the use of human anatomical substances and/or human data, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the US Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (DOD) regulations are met.

Concurrent with the US Army Medical Research Acquisition Activity (USAMRAA) 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 funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

B. Safety Program Documents

The Principal Investigator Safety Program Assurance form will be requested prior to award negotiations.

A Facility Safety Plan from each PI's Organization is required; it will be requested at award negotiations. A Facility Safety Plan from the PI's 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. If the PI's organization is not listed on the website, contact the organization's Facility Safety Director/Manager to initiate completion of the organization-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.amedd.army.mil/assets/docs/sse/SafetyAppendix093008.pdf.

If multiple research sites/organizations are funded in the proposal, a Facility Safety Plan for each site/organization not listed in the aforementioned website will be requested at a later date.

C. Research Involving the Use of Animal or Human Participants and/or Data, including Human Anatomical Substances

1. General Information:

All USAMRMC supported research involving the use of animals or human subjects are required to be reviewed for compliance with appropriate regulations by the USAMRMC

Office of Research Protections (ORP). Submissions should be sent to USAMRMC ORP after local institutional approvals are obtained.

For questions related to both animal and human subjects, please call 301-619-7550 to be connected with an appropriate individual for assistance.

2. Specific Information Pertinent to Animal Studies:

The ORP office responsible for animal research is the Animal Care and Use Review Office (ACURO). Specific documents relating to the use of animals in the proposed projects will be requested if the proposal is selected for funding (these documents should not be submitted with the proposal). The ACURO must review and approve all animal use prior to the start of working with animals. PIs must complete and submit the animal use appendix titled "Research Involving Animals," found on the ACURO website: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_animalappendix.

Allow 2 to 4 months for regulatory review and approval processes for animal studies. Specific requirements for projects involving animals can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1.

3. Specific Information Pertinent to Studies Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

For each investigation involving human subjects, the Director of ORP will designate as the responsible office either ORP Clinical Investigations Regulatory Office (CIRO: (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.ciro),

or ORP Human Research Protection Office (HRPO): (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).

Exempt human subjects investigation needs a determination from the PI's local Institutional Review Board (IRB) as well as the ORP at USAMRMC.

All DOD-funded research involving human subjects and human biological substances must be evaluated by a headquarters-level administrative review (HLAR) and be approved by the USAMRMC ORP in addition to the local IRB. ***The ORP is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and may require information in addition to that supplied to the local IRB.*** Documents related to the use of human subjects or human anatomical substances will be requested if the proposal is selected for funding (these documents should not be submitted with the proposal). During the regulatory review process for investigations involving human subjects, the recommendations of HLAR must be addressed and approved by the local IRB. It is strongly recommended that investigators carefully read the "Guidelines for Investigators" found at https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo (specifically, pages 28-47 for protocol and consent guidance). The time to approval depends greatly on adherence to these guidelines in a clear and comprehensive manner. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.

Requirements: 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. The Guidelines for Investigators provides important information regarding the appropriate elements that should be contained within the protocol and the consent form.

ORP-specific language must be inserted into the consent form, and ORP reporting requirements must be included. This information can be found in the guidelines.

Personnel involved in human subjects research must have appropriate training in the protection of human subjects. Documentation confirming that this training has been completed will be required during the regulatory review process.

Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; http://www.dtic.mil/biosys/downloads/title10.pdf). 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."

This statute is only applicable to certain intervention studies. 10 USC 980 does not apply to retrospective studies, observational studies, blood draws, and tissue collections.

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."* If several protocols exist under the same application, the Secondary Protocol ID number must be designated *"CDMRP-CDMRP Log Number-A, B, C, etc."* Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health (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 the U.S. Public Law 110-85.

APPENDIX 6

ACRONYM LIST

ACURO	Animal Care and Use Office
ADP	Automated Data Processing
ALSRP	Amyotrophic Lateral Sclerosis Research Program
AOR	Authorized Organizational Representative
ARP	Autism Research Program
AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
BMFRP	Bone Marrow Failure Research Program
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
cGMP	Current Good Manufacturing Practices
CIRO	Clinical Investigations Research Office
COI	Conflict of Interest
CR	Contract Representative
CRADA	Cooperative Research and Development Agreement
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
DPI	Dots per inch
DUNS	Data Universal Number System
EIN	Employer Identification Number
EPLS	Excluded Parties List System
ET	Eastern Time
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GSFARP	Genetic Studies of Food Allergies Research Program
GWIRP	Gulf War Illness Research Program
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HLAR	Headquarters-Level Administrative Review
HRPO	Human Research Protection Office
IDE	Investigational Device Exemption
IND	Investigational New Drug
IP	Integration Panel
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
JPRP	Joint Programmatic Review Panel

JSLIP	Joint Senior Leadership Integration Panel
LAR	Legally Authorized Representative
LCRP	Lung Cancer Research Program
LOI	Letter of Intent
M	Million
MB	Megabyte
MNC-I	Multi-National Corps – Iraq
MPEG	Moving Picture Experts Group
MSRP	Multiple Sclerosis Research Program
MTF	Medical Treatment Facility
NIH	National Institutes of Health
NFRP	Neurofibromatosis Research Program
OCRP	Ovarian Cancer Research Program
OMB	Office of Management and Budget
ORP	Office of Research Protections
PCRP	Prostate Cancer Research Program
PD	Project Director
PDF	Portable Document Format
PH/TBIRP	Psychological Health/Traumatic Brain Injury Research Program
PI	Principal Investigator
P.L.	Public Law
POC	Point of Contact
PRCRP	Peer Reviewed Cancer Research Program
PRMRP	Peer Reviewed Medical Research Program
PRORP	Peer Reviewed Orthopaedic Research Program
R&R OPI	Research & Related Other Project Information
SCIRP	Spinal Cord Injury Research Program
SOW	Statement of Work
SPORE	Specialized Programs of Research Excellence
TIFF	Tagged Image File Format
TIN	Tax Identification Number
TRL	Technology Readiness Level
TSCRP	Tuberous Sclerosis Complex Research Program
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
VA	Veterans Affairs
WAV	Waveform Audio