Application Instructions & General Information

Department of Defense Congressionally Directed Medical Research Programs

Tuberous Sclerosis Complex Research Program

Clinical and Translational Research Award

Funding Opportunity Number: W81XWH-09-TSCRP-CTRA

Table of Contents

I. HELPFUL INFORMATION 2
- A. Contacts 2
- B. National Technical Information Service 3
- C. Tips for Success 3
- D. New Submission Requirements for Fiscal Year 2009 3

II. SUBMISSION PROCESS 3
- A. Step 1 – Pre-Application Submission 4
- B. Step 2 – Application Submission 5

APPENDIX 1 Eligibility Information 22
APPENDIX 2 Formatting Guidelines 23
APPENDIX 3 Administrative Actions 24
APPENDIX 4 Grants.gov Instructions 26
APPENDIX 5 Administrative Information 28
APPENDIX 6 Instructions for Regulatory Requirements 32
APPENDIX 7 Instructions for Reports 37
APPENDIX 8 Acronym List 38
APPENDIX 9 Forms 40
1. Biographical Sketch 40
2. Detailed Budget and Justification 43

These instructions apply only to the mechanism listed above.

I. HELPFUL INFORMATION

A. Contacts

1. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. 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
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

2. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time (ET).

Phone: 301-682-5507
Website: https://cdmrp.org
Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort, and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

C. Tips for Success

- Use a Grants.gov-compatible version of Adobe Reader when opening, completing, or submitting the application package.
- Obtain or confirm the organization's DUNS number (https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) well before the application submission deadline.
- Obtain or confirm the organization's registration with the Central Contractor Registry (CCR) (http://www.ccr.gov/) well before the application submission deadline.
- Request "send me change notification emails" from Grants.gov (http://www.grants.gov/).
- Complete the pre-application submission before the mandatory pre-application deadline; otherwise, the pre-application will remain in draft status **(*NOTE: "Submit" button must be pressed for pre-application to be complete*)**.
- Use the correct Grants.gov application package ***(NOTE: Each Program Announcement/Funding Opportunity requires a specific application package).***
- Upload attachments into correct Grants.gov forms.
- Submit attachments as PDF documents.
- Submit an application 48-72 hours before the application submission deadline so Grants.gov can provide notification of errors and allow for resubmission of application package.

D. New Submission Requirements for Fiscal Year 2009 (FY09)

- Application Submission: The Grants.gov application package now uses PDF forms. A compatible version of Adobe Reader is required to submit the application package.
- The Detailed Budget and Justification must be submitted in the Attachments Form.

II. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) an application submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

A. Step 1 – Pre-Application Submission

Application submission will not be accepted unless the pre-application process is completed by the pre-application deadline. The PI and organization identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

Pre-application Components and Submission

All pre-application components must be submitted electronically through the CDMRP eReceipt system by **5:00 p.m. ET on the deadline identified in the specific Program Announcement/ Funding Opportunity**. Material submitted after the pre-application submission deadline, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet this deadline shall result in pre-application rejection and subsequent application rejection.

The pre-application consists of the following components:

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

2. **Proposal Contacts:** 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.

3. **Collaborators and Conflicts of Interest (COI):** To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project including collaborators, consultants, and subawardees. Add all individuals outside of the application who may have a COI in the review of this application, and choose "COI" from the drop-down list. Inclusion of the Program's FY09 Integration Panel (IP) members in any capacity in the project narrative, budget, or supporting documentation, with the exception of References Cited, is considered a COI and will result in administrative withdrawal of the application. A list of the Program's FY09 IP members may be found at http://cdmrp.army.mil/research

4. **Letter of Intent (LOI) Narrative: One-page limit.** The LOI Narrative page limit is inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The narrative should be a brief description of the research to be conducted. LOI Narratives are used for program planning purposes and will not be reviewed during either the peer or programmatic review sessions.

5. **Formatting Guidelines and Submission:** All pre-application documents must be individual PDF files, in accordance with the formatting guidelines, and uploaded under the "Required Files" tab of the CDMRP eReceipt system.

6. **PI Responsibilities:** The PI is responsible for completing the pre-application submission (by completing the "Submit Pre-application" tab) in the CDMRP eReceipt system, and for reviewing the submission to ensure compliance with the Program Announcement/Funding Opportunity requirements.

7. **CR/Authorized Organizational Representative (AOR) Responsibility:** The pre-application does not require approval by either the CR or AOR of the organization before submission.

B. Step 2 – Application Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. Applications must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

Submission of an application through Grants.gov has several institutional requirements (see Appendix 4), which may take several weeks to complete.

The PI and organization identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

Please note that* Grants.gov *may take at least 48-72 hours to process application submissions and notify the applicant institution of any errors. Submit applications as early as possible to allow sufficient time for error correction and resubmission as a "Changed/Corrected Application" prior to the deadline. Grants.gov may allow submission of applications after the deadline and may send a message that the application is being processed. In this case, however, notification will be sent at a later date, stating that the application was not submitted on time and will not be accepted by Grants.gov.

NEW for FY09: Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed in Appendix 3, Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

Application Components and Submission

Each application submission requires the completion of a Grants.gov application package of forms and attachments identified in Grants.gov (www.grants.gov) for the specific funding opportunity.

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.

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., TS09####)** acquired during the pre-application process. ***Do not fill in the Competition ID.***

Figure 1. Application Filing Name.

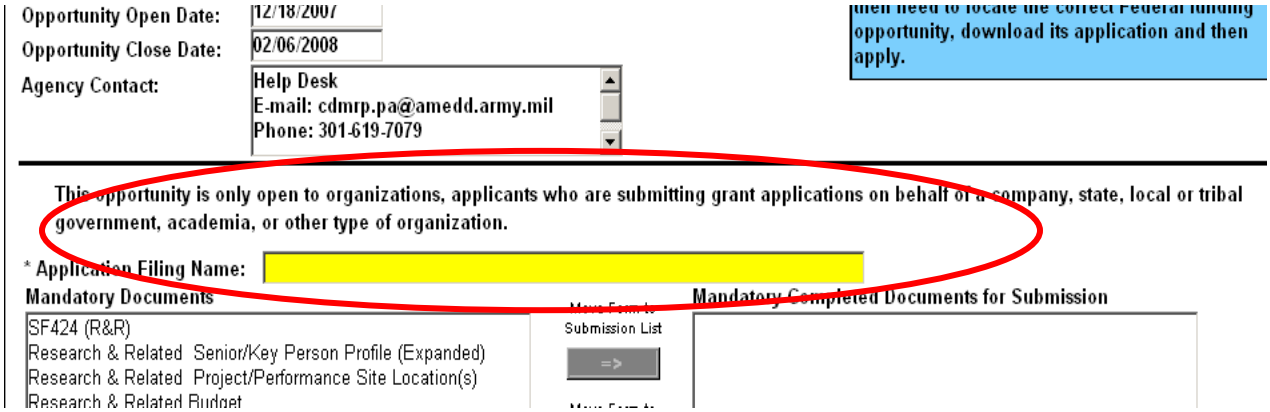


Table 1 lists the forms required for this Grants.gov application package. Several documents must be attached to the application forms. Requirements for each attachment are described below and in the specific Program Announcement/Funding Opportunity.

Table 1. Required Forms for Grants.gov Submission.

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	None	Enter the appropriate information in data fields
Attachments Form	Project Narrative	Upload as Attachment 1 (Narrative.pdf)
	Supporting Documentation	Upload as Attachment 2 (Support.pdf)
	Technical Abstract	Upload as Attachment 3 (TechAbs.pdf)
	Public Abstract	Upload as Attachment 4 (PublicAbs.pdf)
	Statement of Work (SOW)	Upload as Attachment 5 (SOW.pdf)
	Detailed Budget and Justification	Upload as Attachment 6 (Budget.pdf)
	Impact Statement	Upload as Attachment 7 (Impact.pdf)
	Statement of Collaboration (if applicable)	Upload as Attachment 8 (Collaboration.pdf)
	Clinical Protocol (if applicable)	Upload as Attachment 9 (Protocol.pdf)
	Federal Agency Financial Plan (if applicable)	Upload as Attachment 10 (FedFin.pdf)
	Subaward Detailed Budget and Justification (if applicable)	Upload as Attachment 11-15 (SubBudget_Organization.pdf)
Research & Related Senior/Key Person Profile (Expanded)	PI Biographical Sketch	Attach to PI Biographical Sketch field (Biosketch_LastName.pdf)
	PI Current/Pending Support	Attach to PI Current & Pending Support field (Support_LastName.pdf)
	Key Personnel Biographical Sketches	Attach to Biographical Sketch field for each senior/key person (Biosketch_LastName.pdf)
	Key Personnel Current/Pending Support	Attach to Current & Pending Support field for each senior/key person (Support_LastName.pdf)
Research & Related Project/Performance Site Location(s) Form	None	Enter the appropriate information in data fields

NEW FOR FY09:

As the Grants.gov application package for this award mechanism uses Adobe Reader forms, you must have a compatible version of Adobe Reader in order to submit the application package. You will receive an error message and your application will be rejected by Grants.gov if you open, complete, or submit the application package with software other than a compatible version of Adobe Reader. If you collaborate on the application package with your peers, you must ensure they also have a compatible version of Adobe Reader.

While Grants.gov claims to be compatible with Adobe Acrobat Professional, you must use the Adobe Reader version recommended by Grants.gov. This compatible version of Adobe Reader is available for downloading at no cost on the Grants.gov website: http://www.grants.gov/help/download_software.jsp.

Grants.gov will reject an application package that is opened at any point in time with an incompatible version of Adobe Reader. If your application is rejected by Grants.gov, due to use of an inappropriate Adobe Reader version, you must download a new application package, open and complete the package manually, and then submit the new package using a supported version of Adobe Reader.

Visit the following website to verify that your Adobe Reader version is compatible with Grants.gov: http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp.

1. SF-424 (R&R), Application for Federal Assistance Form

This form is required for each application. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this application package. The form is self-explanatory, with the following exceptions:

- **Applicant Identifier** box should be filled in with the submitting Institution's Control Number.
- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions, the "Application" box should be chosen. For changes that must be made after the original submission, the complete application package must be resubmitted, with the "Changed/Corrected Application" box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable.
- **Block 4 – Federal Identifier Box.** Populated by Grants.gov for an original application. If "Changed/Corrected Application" is entered in Block 1, then manually enter the Grants.gov tracking number (i.e., the Grant ID Number assigned to the original application).

- **Block 5 – Applicant Information.** This is the information for the Applicant Organization, not an individual. The "Person to be contacted on matters involving this application" is the CR or Business Official. This is not the Project Director (PD)/Principal Investigator (PI).
- **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 a foreign institution, enter 44-4444444.
- **Block 7 – Type of Applicant.** This is for the Applicant Organization, not an individual. This is not the PD or PI.
- **Block 8 – Type of Application.** For all submissions, the "New" box must be chosen.
- **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** – **Areas Affected by Project**. List the largest political entities affected by the project (e.g., state, county, city). Enter N/A for not applicable.
- **Block 13 – Proposed Project.** The start date should be 9 months to a year from the deadline for application submission for this award mechanism.
- **Block 14 – Congressional Districts Of.** If applying from a foreign institution, enter "00-000" for both applicant and project.
- **Block 15 – Project Director/Principal Investigator Contact Information.** Enter information for the individual (PI) responsible for the overall scientific and technical direction of this application.
- **Block 16 – Estimated Project Funding**. Enter the total funds (direct + indirect costs) requested for the entire performance period of the project.
- **Block 17 – Is Application Subject to Review by State Executive Order 12372 Process?** Choose option "b. NO, program is not covered by E.O.12372."
- **Block 18 – Complete Certification.** Check "I agree" box to provide the required certifications and assurances**.**
- **Block 19 – Authorized Organizational Representative (AOR).** The AOR is the individual with the organizational authority to sign for an application. The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. ***Hard copies of applications will not be accepted.***
- **Block 20 – Pre-application.** Do not attach any documents to this block.

Each attachment to the Grants.gov application forms must be a single PDF file in accordance with the formatting guidelines.

Failure to meet Program Announcement/Funding Opportunity requirements may result in Administrative Actions as indicated in Appendix 3.

2. Attachments Form

The following information must be included as attachments to this form:

Attachment 1: Project Narrative: Named "Narrative.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, cartoons, and other relevant information needed to judge the application. Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Project Narrative, page limit, and peer review criteria.

Attachment 2: Supporting Documentation: 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. Submitting such material may be grounds for administrative rejection of the application. ***The Supporting Documentation attachment is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the application.***

a. References Cited: No page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

b. Acronyms and Symbol Definitions: No page limit. Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.

c. Facilities & Other Resources: No page limit. Describe the facilities available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.

d. Description of Existing Equipment: No page limit. Include a description of existing equipment available to be used for the proposed research project.

e. Publications and/or Patent Abstracts: Include up to five relevant publication URLs and/or patent abstracts. If publications are not publicly available, documents

must be scanned at the lowest resolution (100 to 150 DPI) and included. Extra items will not be reviewed.

f. Letters of Institutional Support: Two-page limit per letter. Provide letter(s) of institutional support, signed by the Department Chair or appropriate institution official, that reflects the laboratory space, equipment, and other resources available for this project.

g. Letters of Collaboration (if applicable): Two-page limit per letter. Provide a signed letter from each collaborating individual or institution that will demonstrate the PI has the resources necessary for the proposed work. If applying for the higher level of funding, the collaborator(s) must provide a letter of collaboration describing his/her involvement in the proposed work. It should be clear that the success of the project depends on the unique skills and contributions of each partner.

h. Intellectual and Material Property Plan (if applicable): No page limit. Provide a plan for resolving intellectual and material property issues among participating institutions.

Attachment 3: Technical Abstract: Single PDF file 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.***

Technical Abstract: One-page limit. Use the outline below.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Briefly describe how the proposed project will have an impact on neurofibromatosis research or patient care.

Attachment 4: Public Abstract: Single PDF file 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.***

Public Abstract: One-page limit. The public abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. For guidance on how to write a scientific piece for the general public, please see http://www.plainlanguage.gov/.

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
    - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of research?

Attachment 5: Statement of Work (SOW): Three-page limit, named "SOW.pdf."

SOW structure: The SOW is a concise restatement of the research proposal that outlines and establishes the PI's performance expectations and timeline during the period of performance of the award. Although some allowance is made for problems encountered and uncertainties that are part of research, the PI is expected to meet the provisions and milestones in the SOW. Failure to meet deliverables as defined by tasks may result in withdrawal of funds.

The SOW should be a series of relatively short statements that outline step-by-step each of the major goals or objectives of the proposed research/services. The SOW should only describe work for which funding is being requested by this application.

As appropriate, the SOW should:

- Describe the work to be accomplished and deliverables as tasks that relate to one another, to the proposed specific aims, and to the period of performance.
    - Indicate the number of research subjects (animal or human) and/or anatomical samples projected or required for each task.
    - Identify methods, outcomes, products, and deliverables for each phase of the project.
- Identify the timeline and milestones for the work over the period of the proposed effort.
    - Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.
    - Allow 2 to 4 months for regulatory review and approval processes for animal studies.
- If the mechanism allows clinical trials, indicate time required for human use approval and submission of applicable documents (i.e., Investigational New Drug [IND] and Investigational Device Exemption [IDE]) to the Food and Drug Administration (FDA) or appropriate agency. The Government reserves the right to

withdraw funding if IND/IDE approval is not received within 6 months of the award.

- Include the following information for each study site/subaward site that will be actively participating in the study:
  - Collaborator, consultant, and/or subawardee name,
  - Institution,
  - Institution address, and
  - Animal or human use at this site.

Suggested SOW format: The SOW should include a list of tasks that relate to the specific aims, with a brief description of each task and subtask to include the items requested above and a concise timeline. There is no limit to the number of tasks and subtasks that are described within the three-page SOW length limit. Below is a suggested format:

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 concise timeline should account for the duration by quarter (Q) or year and scheduling relationships of the major tasks identified in the descriptive SOW above. A Gantt chart or timeline may be used, such as the example below in Table 2.

Table 2. Example of Gantt Chart for SOW.

	Q1 or Year 1	Q2 or Year 2	Q3 or Year 3
Specific Aim #1 – Text from project narrative			
Task 1 Short title, e.g., Development of …			
1.a Short title, e.g., Prepare…	University of X		
Milestone #1 Animal and Human Use approvals	University of X & Y		
1.b Short title, e.g., Perform…	Animals used e.g., 180 rats University of Y		
1.c Short title, e.g., Analyze…	University of Y		
Milestone #2 Technique X protocol			
Specific Aim #2 – Text from project narrative			
Task 2 Short title, e.g., Characterization of …			
2.a Short title, e.g., Hormone dose studies		Cell lines used University of Y	Animals used
2.b Short title, e.g., Drug toxicity evaluation	Animals used University of X	Animals used University of Y	
2.c Short title, e.g., Perform…		Human anatomical samples used University of Y	
2.d Short title, e.g., Analyze…		University of X	
Milestone #3 Publication			Journal X

Attachment 6: Detailed Budget and Justification: No page limit, named "Budget.pdf"

An estimate of the total research project cost, with a breakdown by category and year, must accompany each application. Use the Detailed Budget and Justification template that is provided in Appendix 9 and also 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.

- You may propose using the entire maximum direct cost amount for a project that will be less than the maximum period of performance.
- Regardless of the period of performance proposed, you may not exceed the maximum direct cost.
- The program does not allow applications for renewal of awards or supplementation of existing awards.

All costs must be entered in US dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to US

dollars, and justification/basis for the conversion rate used. All costs must be reasonable and adequately supported.

The following cost regulations and principles must be adhered to regarding budget calculations:

- **Maximum Obligation:** The USAMRMC does not amend 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/index.html).
  - **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.

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

Qualifications of the PI and other professional personnel, and the amount of time that they will devote to the research are important factors in selecting applications for funding. For all personnel identified on the budget form, list the percentage of effort to be dedicated to this project.

- **Name:** Beginning with the applicant, 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 institutional base salary for each individual listed for the project.
- **Percentage of Effort on Project:** The applicant's qualifications and the amount of time that he/she and other professional personnel will devote to the research are important factors in selecting research applications for funding. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid collaborators and consultants.
- **Salary Requested:** Enter the salary in whole US dollars for each position for which funds are requested. Calculate the salary request by multiplying an individual's institutional base salary by the percentage of effort on the project.
- **Fringe Benefits:** Fringe benefits for each position may be requested in accordance with organizational guidelines, provided the costs for all sponsors are treated consistently by the applicant's organization. Provide documentation to support the fringe benefits.
- **Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

Other Direct Costs

- **Major Equipment Description:** It is the Department of Defense policy that all commercial and nonprofit recipients provide the equipment needed to support 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.

  An itemized list of proposed permanent equipment is required, 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 justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification, to 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.
- Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

- **Travel Costs**
  - **Travel costs to attend one scientific/technical meeting.** Costs should not exceed $1,800 total per year.
  - **Travel costs associated with the execution of the proposed work (if applicable).** Reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these travel costs should be provided. 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 to CDMRP-required meetings (if applicable).** Costs should be reasonable.
- **Materials, Supplies, and Consumables:** The justification (to be included in 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, in the Budget Justification, include 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:** Enter 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. ***Provide a Detailed Budget and Justification for each subaward as a separate attachment.***
- **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. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the proposed research.
- **Other Expenses**: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), communication costs, and institutionally 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. Institutionally provided services should be supported by the organization's current cost/rate schedule. These items should be explained and justified in the Budget justification.

Total Direct Costs: Self-explanatory**.**

Indirect Costs (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 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, 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 self-explanatory.

Fee: A profit or fixed fee is not allowable on awards or on subawards.

Budget Justification: Each item in the budget for the entire period of performance must be clearly justified in the Budget Justification section of the Detailed Budget Form. **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.**

Attachment 7: Impact Statement (if required): One-page limit, named "Impact.pdf." Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Impact Statement. The Impact Statement will be available for both peer review and programmatic review.

Attachment 8: Statement of Collaboration (if applicable): One-page limit, named "Collaboration.pdf." For applications requesting the higher level of funding, the PI must submit a statement identifying the collaborating investigator and addressing all criteria described in Section II.B of the Program Announcement/Funding Opportunity. It should be clear that the success of the project depends on the unique skills and contributions of each partner. The Statement of Collaboration will be available for both peer and programmatic review.

Attachment 9: Clinical Protocol (if applicable): No page limit, named "Protocol.pdf." If the work proposed includes a clinical trial, a clinical protocol must be submitted. Refer to the Program Announcement/Funding Opportunity for instructions for preparing the Clinical Protocol and supporting documentation, and for Clinical Protocol review criteria.

Attachment 10: Federal Agency Financial Plan (if applicable): No page limit, named "FedFin.pdf." Applications from Federal agencies should provide a plan delineating how all funds will be obligated by September 30, 2010, 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 institutions, and universities.

Attachment 11-15: Subaward Detailed Budget and Justification (if applicable): No page limit. Detailed Budget and Justification for each subaward (subgrant or subcontract) must be submitted. Use the Detailed Budget and Justification template that is provided in Appendix 9 and also available for download on the Full Announcement page for this Program Announcement/Funding Opportunity in Grants.gov. Refer to the instructions listed under Attachment 6 for Detailed Budget and Justification. Name each file "SubBudget_Organization.pdf" where "Organization" is the name of the organization receiving the subaward. 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 if the proposed costs are reasonable for the proposed research effort. The following information must be provided on subawards:

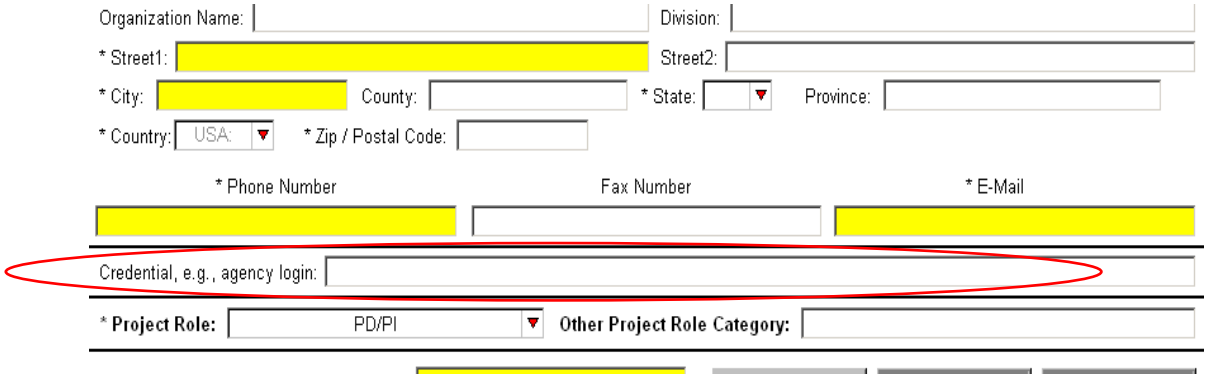
- Identification of the type of subaward to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subrecipient, if known, and an explanation of why and how the subcontractor or subrecipient was selected or will be selected;
- Whether the subaward will be competitive;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

3. 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: Four-page limit. Suggested format is provided in Appendix 9. Name the PDF file "Biosketch_LastName.pdf" where "LastName" is the name of the PI.

b. PI Current/Pending Support: No page limit. 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:

- 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
- List of the specific aims

Provide justification for the requested support and identify where the projects overlap or parallel. If no current support exists, enter "None." Updated current and pending support will be required during award negotiations.

c. Key Personnel Biographical Sketches: Four-page limit per individual. Suggested format is provided in Appendix 9. 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: No page limit. 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.

4. Research & Related 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. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Please note that each additional research site requesting funds will require a subcontract budget.

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.)

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution and meet the specific Program Announcement/Funding Opportunity requirements.

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

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI): A Department of Defense goal is to allocate funds for the Congressionally Directed Medical Research Programs (CDMRP) peer reviewed research to fund applications from HBCU/MI. This provision is based on guidance from Executive Orders 12876, 12900, and 13021. Applications are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the Program Announcement/Funding Opportunity is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

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

The application 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 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. Since some reviewers work from black and white printed copies, Principal Investigators may wish to include text directing the reviewer to the electronic file for parts of the application that may be difficult to interpret when printed in black and white. 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.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB.

All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded as a PDF file.

APPENDIX 3

ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative or Clinical Protocol (if applicable) is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Clinical Protocol.
- Documents not requested will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 Integration Panel (IP) member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at http://cdmrp.army.mil/research
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget exceed maximum allowed by award mechanism.
- Inclusion of URLs with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the US Army Medical Research Acquisition Activity Contracting/Grants Officer for a determination of the final disposition of the application.

APPENDIX 4

GRANTS.GOV INSTRUCTIONS

A. Grants Policy Committee

Applications requesting funding from the Congressionally Directed Medical Research Programs (CDMRP) will be submitted through the Federal Government's single entry portal, Grants.gov. The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted in November 1999. The purposes of the P.L. 106-107 were to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

Individual Program Announcements/Funding Opportunities and required forms can also be found on this website. As in previous years, award mechanisms requiring pre-applications including Letter of Intent Narratives, preproposals, nominations, and/or confidential letters will be submitted through the CDMRP eReceipt system at https://cdmrp.org.

B. Grants.gov

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between Principal Investigators (PIs) and the Federal agencies that manage grant funds. The grant community, including state, local, and tribal governments, academia and research institutions, commercial firms, and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

In compliance with P.L. 106-107, the United States Army Medical and Materiel Command requires applications submitted in response to the Program Announcement/Funding Opportunity to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit applications through the Grants.gov portal. Individual PIs DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register.

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

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 (http://fedgov.dnb.com/webform/displayHomePage.do). If an organization does not have a

DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/index.jsp). 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 before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates institution 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, PIs should verify the status of their organization's CCR registration well in advance of the application submission deadline.***

Register by calling the CCR Assistance Center at 888-227-2423 or register online at http://www.ccr.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. With the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of the organization. Allow a minimum of 5 business days to complete the entire CCR registration. If the organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service (IRS).

Foreign 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. AOR must be registered with Grants.gov: Before submitting an application, an organization representative needs to register to submit on behalf of the organization at Grants.gov - https://apply.grants.gov/OrcRegister. An organization's E-Business point of contact (POC), identified during CCR registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit applications without permission. The AOR's username and password serve as "electronic signatures" when an application is submitted on Grants.gov.

Note: In some organizations, a person may serve as both an E-Business POC and an AOR.

An AOR must first register with the Grants.gov credential provider at https://apply.grants.gov/OrcRegister to obtain a username and password. The AOR must then register with Grants.gov for an account at https://apply.grants.gov/GrantsgovRegister. 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 5

ADMINISTRATIVE INFORMATION

A. Administrative Requirements

Awards are made to organizations, not individuals. Thus, a Principal Investigator (PI) must submit an application through, and be employed by, an organization to receive support. An organization must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (2 Code of Federal Regulations Part 215 and Department of Defense [DOD] Grant and Agreement Regulations) to be eligible for an award.

Unless restricted by the specific Program Announcement/Funding Opportunity, a change in institutional affiliation will require the PI to resubmit the entire application packet through his/her new institution to include any regulatory documentation that may require protocols, etc., to be approved for the new institution. The PI's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting and regulatory review and a subsequent delay in resuming work on the project. Unless also restricted, changes in PI will be made at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

B. Duplicate Submissions

Submission of the same research project to different award mechanisms within the same program or to other Congressionally Directed Medical Research Programs (CDMRP) programs is discouraged. The Government reserves the right to reject duplicative applications.

C. Integrity of Review Process

The scientific peer review, military relevance review, and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that application and evaluation information will not be disclosed outside the panel.

Violations of the nondisclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the scientific peer review, military relevance review, and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

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 US Army Medical Research and Materiel Command (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. Funded proposals 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. Award Notices

Each PI will receive notification of the award status of his/her application. A copy of the scientific peer review and military relevance review summary statements, if applicable, will be posted to the CDMRP eReceipt system. PIs can expect to receive this notification approximately 4 weeks after programmatic review.

F. Inquiry Review Panel

PIs may submit a letter of inquiry to the US Army Medical Research Acquisition Activity (USAMRAA) in response to funding decisions. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel. They review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred and, if so, what action should be taken.

G. Award Negotiation

Prior to award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, and regulatory documents related to human and animal studies and other documents (Appendix 6) will be requested from the PI. Also at that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the Contracting Representative or Authorized Organizational Representative (AOR) at the organization.

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the PI's institution. Additional documentation and justifications related to the budget may also be required.

Only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of an application or to support research should be inferred from discussions with a technical project officer. PIs who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2010. The award start date will be determined during the negotiation process.

The Government requires reports (Appendix 7) to be submitted by each PI for continuation of the research and funding.

H. 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.

I. 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.

J. 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 such 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.

K. *New for FY09:* 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.

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 share 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. By sharing data and research resources, duplication of very expensive and time-consuming efforts can be avoided, and the CDMRP will be able to support more investigators than if these resources were to be generated in duplicate by more than one CDMRP-funded investigator. The CDMRP believes that such sharing allows the expeditious translation of research results into knowledge, products, and procedures to improve human health.

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

APPENDIX 6

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/institutions 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 Institution is required; it will be requested at award negotiations. A Facility Safety Plan from the PI's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/docs/rcq/sohd/Facility_Safety_Plan_Approved_Institutions.pdf. If the PI's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.amedd.army.mil/docs/rcq/SafetyAppendix093008.pdf.

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

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested by the Congressionally Directed Medical Research Programs (CDMRP) if the proposal is selected for funding (these documents should not be submitted with the application). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP), 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 "ACURO Animal Use Appendix for Research Involving Animals," which can be found on the ACURO website https://mrmc.amedd.army.mil/AnimalAppendix.asp Allow 2 to 4 months for regulatory review and approval processes for animal studies.

Specific requirements for research involving animals can be found at https://mrmc.amedd.army.mil/rodorpaurd.asp.

D. Research Involving Human Subjects or Biological Substances, Including the Use of Human Anatomical Substances and/or Human Data

For all other studies, documents related to the use of human subjects, anatomical substances, and/or data will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the application).

During the regulatory review process for research involving human subjects, the recommendations of the Human Research Protection Office (HRPO) must be considered by the local Institutional Review Board (IRB). It is strongly recommended that investigators carefully read the "Guidelines for Investigators" found at https://mrmc.amedd.army.mil/docs/RCQ/GuidelinesForInvestigators.pdf (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. An initial review by the HRPO before local IRB approval will be considered on a case-by-case basis.

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

The following links are guidances for the PI regarding submission of protocols to the USAMRMC ORP, HRPO, and should be reflected in the protocol packet:

Requirements:

1. Protocol: 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/rodorphrpo.asp. It is imperative that the required language pertaining to DOD reporting requirements be added to the protocol. ***Note:*** 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.

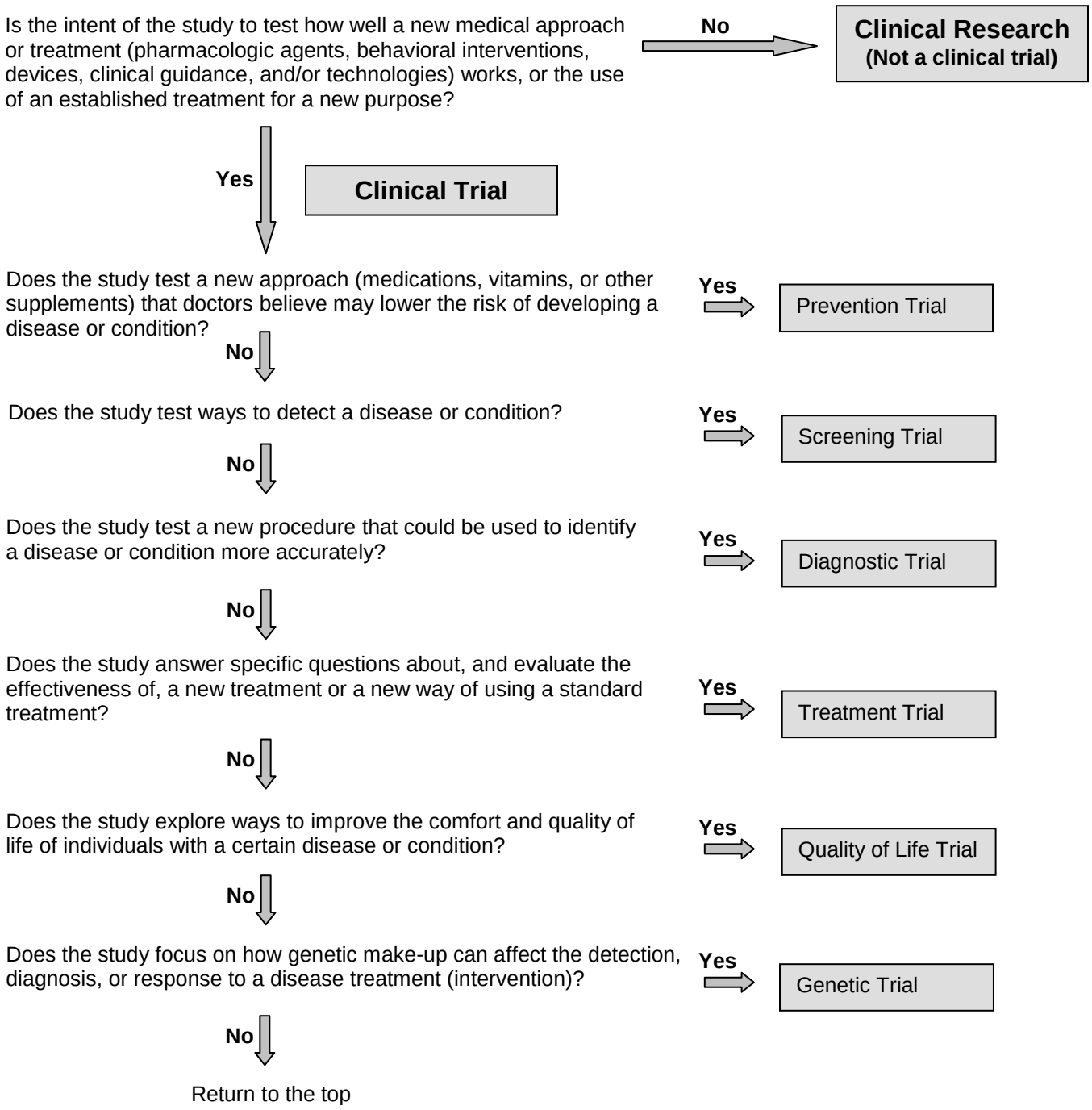
2. Informed Consent Form: Elements to include in the informed consent form can be found at https://mrmc.amedd.army.mil/docs/rcq/GuidelinesForInvestigators.doc#p41SecF, and an informed consent form template is located at https://mrmc.amedd.army.mil/docs/rcq/consentform_template.pdf. ***Note:*** Language

regarding the DOD as funding source and the role of USAMRMC in reviewing research records must be documented in the consent form.

3. 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) applicable to DOD-sponsored research before writing a research protocol. 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 means that an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors), and thus relying on a legally authorized representative as defined by state law, may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, when a subject may benefit directly from medical treatment or surveillance beyond the standard of care. PIs should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative. Language stating how the research is beneficial to the subject must be included in an appropriate location in the consent form.

4. 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.

5. Clinical Trial Decision Tool: The decision tree targets ***studies involving human subjects, anatomical samples, or behavior that can be linked to the subject,*** thereby requiring informed consent from the volunteer. Studies must be approved through a regulatory review process conducted by HRPO and the local IRB. This decision tree will direct the PI through a series of questions designed to assist the identification of clinical research that is a clinical trial.


Is the intent of the study to test how well a new medical approach or treatment (pharmacologic agents, behavioral interventions, devices, clinical guidance, and/or technologies) works, or the use of an established treatment for a new purpose?
No
Clinical Research
(Not a clinical trial)
Yes
Clinical Trial
Does the study test a new approach (medications, vitamins, or other supplements) that doctors believe may lower the risk of developing a disease or condition?
Yes
Prevention Trial
No
Does the study test ways to detect a disease or condition?
Yes
Screening Trial
No
Does the study test a new procedure that could be used to identify a disease or condition more accurately?
Yes
Diagnostic Trial
No
Does the study answer specific questions about, and evaluate the effectiveness of, a new treatment or a new way of using a standard treatment?
Yes
Treatment Trial
No
Does the study explore ways to improve the comfort and quality of life of individuals with a certain disease or condition?
Yes
Quality of Life Trial
No
Does the study focus on how genetic make-up can affect the detection, diagnosis, or response to a disease treatment (intervention)?
Yes
Genetic Trial
No
Return to the top

6. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells: Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g 2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the application.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

APPENDIX 7

INSTRUCTIONS FOR REPORTS

The Government requires reports to be submitted by each Principal Investigator for continuation of the research and funding. The specific reports due to the Government will be described in each assistance agreement. Report requirements can be found at https://mrmc-www.army.mil, under "Links and Resources." ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

A. Research Progress Reports

Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. Additional reports may be required as stipulated during award negotiations. Copies of all scientific publications and patent applications resulting from Congressionally Directed Medical Research Programs funding should be included in the progress report. The Government reserves the right to request additional reports.

B. Fiscal Reports

Quarterly fiscal reports will be required for grants and cooperative agreements to track the expenditure of funds on the research project.

C. Non-Exempt Human Studies Reports

For non-exempt human subjects research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

D. Animal Use Reports

Principal Investigators are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

APPENDIX 8

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
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practices
CAGE	Commercial and Government Entity
COI	Conflicts of Interest
CR	Contract Representative
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
DPI	Dots per inch
DRMRP	Deployment Related Medical Research Program
DUNS	Data Universal Number System
EIN	Employer Identification Number
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GWIRP	Gulf War Illness Research Program
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HIPAA	Health Insurance Portability and Accountability Act
hES	Human Embryonic Stem
HRPO	Human Research Protection Office
HSRRB	Human Subjects Research Review Board
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
mTBI	Mild Traumatic Brain Injury
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
PI	Principal Investigator
P.L.	Public Law
POC	Point of Contact
PRCRP	Peer Reviewed Cancer Research Program
PRMRP	Peer Reviewed Medical Research Program
PTSD	Post-Traumatic Stress Disorder
R&R OPI	Research & Related Other Project Information
SOW	Statement of Work
SPORE	Specialized Programs of Research Excellence
TBI	Traumatic Brain Injury
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

APPENDIX 9

FORMS

1. Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded).			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD(S) OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and also to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

Detailed Budget and Justification

Name of Principal Investigator: _____ _____ _____ ____
Last Name *First Name* *Middle Name* *Suffix*
CDMRP log number: _____
Period of Performance: **From:** _____ **Through:** _____

DETAILED BUDGET FOR YEAR ONE

SENIOR/KEY PERSON & OTHER PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	Principal Investigator						

A. SUBTOTAL PERSONNEL COSTS	$0	$0	$0

Detailed Budget

DETAILED BUDGET FOR YEAR ONE (CONTINUED)	
OTHER DIRECT COSTS	
MAJOR EQUIPMENT (ITEMIZE)	$0
TRAVEL COSTS	$0
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)	$0
CONSULTANT COSTS	$0
SUBAWARD/CONSORTIUM/CONTRACTUAL COSTS (ITEMIZE, INCLUDE TOTAL COSTS INCLUDING DIRECT AND INDIRECT COSTS)	$0
RESEARCH-RELATED SUBJECT COSTS	$0
OTHER EXPENSES (ITEMIZE BY CATEGORY)	$0
B. SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD	**$0**
C. TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (A+B)	**$0**
D. TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD	**$0**
TOTAL COSTS FOR INITIAL BUDGET PERIOD (C+D)	**$0**

Detailed Budget

BUDGET FOR ENTIRE PROPOSED PERIOD OF PERFORMANCE						
BUDGET CATEGORY TOTALS*	**BUDGET YEAR ONE**	**ADDITIONAL YEARS OF SUPPORT REQUESTED**				**TOTAL**
		2nd	**3rd**	**4th**	**5th**	
A. PERSONNEL COSTS	**$0**					**$0**
B. OTHER COSTS	**$0**					**$0**
MAJOR EQUIPMENT	$0					$0
TRAVEL COSTS	$0					$0
MATERIALS, SUPPLIES, AND CONSUMABLES	$0					$0
CONSULTANT COSTS	$0					$0
SUBAWARD/ CONSORTIUM/ CONTRACTUAL COSTS	$0					$0
RESEARCH-RELATED SUBJECT COSTS	$0					$0
OTHER EXPENSES	$0					$0
C. TOTAL DIRECT COSTS	**$0**					
D. TOTAL INDIRECT COSTS	**$0**					
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						**$0**
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						**$0**
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT **THIS AMOUNT MUST MATCH WITH THAT ENTERED ON THE SF 424, BLOCK 16A**						**$0**

*** Itemize all budget categories for additional years on the Justification page that follows.**

Detailed Budget

JUSTIFICATION

FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

Detailed Budget

JUSTIFICATION

FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

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