

# **Application Instructions & General Information**

**Department of Defense Congressionally Directed Medical Research Programs**

**Deployment Related Medical Research Program (DRMRP)**

**Hypothesis Development Award**

**Funding Opportunity Number: W81XWH-08-DRMRP-HDA**

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*These instructions apply only to this mechanism.*

## I. HELPFUL INFORMATION

### A. Contacts

**1. Program announcement (PA), proposal 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](mailto: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.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**3. Grants.gov contacts:** Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to the Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions regarding Grants.gov submissions.

Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: [support@grants.gov](mailto:support@grants.gov)

***Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list 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](http://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. Commonly Made Mistakes

- Not obtaining or confirming the organization's Data Universal Number System (DUNS) number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting help desks until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline, i.e. pre-application remains in draft status (***NOTE: "Submit" button must be pressed for pre-application to be complete.***)
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit a proposal by submission deadline.

## 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) a proposal 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 proposals.

### A. Step 1 - Pre-Application Submission

***Proposal submission will not be accepted unless the pre-application process is completed by the pre-application deadline.*** The PI and Organization identified in the proposal 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](mailto: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. Eastern time 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 proposal rejection.

The pre-application consists of the components discussed below.

- 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 proposal who may have a COI in the review of this proposal, and choose "COI" from the drop-down list. Inclusion of the Program's Fiscal Year 2008 (FY08) Joint Senior Leadership Integration Panel (JSLIP) members in any capacity in the proposal, budget, or supporting documentation, with the exception of References Cited, is considered a COI and will result in administrative withdrawal of the proposal. A list of each of the Program's FY08 JSLIP 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 and should specify the FY08 DRMRP topic area to be addressed. LOI Narratives are used for program planning purposes and will not be reviewed during scientific peer, military relevance, or programmatic review.

**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 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 - Proposal Submission**

***Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline.*** Proposals must be submitted electronically by the AOR through Grants.gov ([www.grants.gov](http://www.grants.gov)). No paper copies will be accepted.

Submission of a proposal through Grants.gov has several institutional requirements, which may take several weeks to complete.

The PI and Organization identified in the proposal 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, please contact the eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

***Please note that Grants.gov may take at least 48-72 hours to process proposal submissions and to 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 proposals after the deadline and may send a message that the application is being processed. However, in this case notification will be sent at a later date, stating that the proposal was not submitted on time and will not be accepted by Grants.gov.

## **Proposal Components and Submission**

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

Fill in the **Application Filing Name** on the first screen of the Grant Application Package (Figure 1) using only the **CDMRP log number** acquired during the pre-application process. **Do not fill in the Competition ID.**

**Figure 1. Application Filing Name.**

The screenshot shows a web-based application form. At the top, there are fields for 'Opportunity Open Date' (12/18/2007) and 'Opportunity Close Date' (02/06/2008). Below these is an 'Agency Contact' section with 'Help Desk', 'E-mail: cdmrp.pa@amedd.army.mil', and 'Phone: 301-619-7079'. A blue callout box on the right contains the text: 'Users need to locate the correct Federal funding opportunity, download its application and then apply.' Below the contact information is a horizontal line, followed by a note: 'This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.' The 'Application Filing Name' field is highlighted in yellow and circled in red. Below this is a 'Mandatory Documents' section with a list of documents: 'SF424 (R&R)', 'Research & Related Senior/Key Person Profile (Expanded)', 'Research & Related Project/Performance Site Location(s)', and 'Research & Related Budget'. A 'Move Form to Submission List' button is visible between the document lists. To the right is a 'Mandatory Completed Documents for Submission' section.

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.**

<b>Form</b>	<b>Attachment</b>	<b>Action</b>
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)
	Statement of Work (SOW)	Upload as Attachment 3 (SOW.pdf)
	Military Relevance Statement	Upload as Attachment 4 (MilRel.pdf)
	Request for Information	Upload as Attachment 5 (Information.pdf)
	Federal Agency Financial Plan (if applicable)	Upload as Attachment 6 (FedFin.pdf)
Research & Related Senior/Key Person Profile (Expanded)	PI Biographical Sketch	Attach to PI Biographical Sketch field (Biosketch_LastName.pdf)
Research & Related Budget Form	Budget Justification for entire performance period	Attach to Section K in budget period one (Justification.pdf)
Research & Related Project/Performance Site Location(s) Form	None	Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets and justifications	Attach a separate budget with justification for each subaward (Justification_LastName.pdf)

Click on “Help Mode” in the Grants.gov PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in the application package (Figure 2).



**Figure 2. Grants.gov Pure Edge Tool Bar.**



### **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 EIN or 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 proposal 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](#).*

*All proposals must comply with the [compliance guidelines](#). Failure to meet compliance guidelines may result in proposal rejection.*

## 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 proposal. 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 proposal. Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Project Narrative, page limits, and review criteria.

*Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, references to the PI or the institution in the project narrative and/or the military relevance statement are prohibited and will result in administrative withdrawal of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed, will result in administrative withdrawal of the proposal.*

*The Project Narrative will be available for peer, military relevance, gap alignment, and programmatic review.*

**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 proposal. *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 proposal.*

**a. References Cited:** List relevant references (*five maximum*) 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.

**Attachment 3: Statement of Work (SOW): Two-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 how each of the major goals or objectives of the proposed research/services will be accomplished. The SOW should only describe work for which funding is being requested by this proposal.

As appropriate, the SOW should:

- Describe the work to be accomplished and deliverables as tasks that relate to one another, to the proposal 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.
- Indicate time required for human use approval and FDA submission of applicable documents (i.e., Investigational New Drug [IND] and Investigational Device Exemption [IDE]).
- 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
  - 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 two-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 Gantt Chart for SOW.**

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

**Attachment 4: Military Relevance Statement: Two-page limit, named “MilRel.pdf.”**

Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Military Relevance Statement. The Military Relevance Statement will be available for military relevance and programmatic review; it will not be available for scientific peer review.

**Attachment 5: Request for Information (RFI) [if applicable]: Four-page limit, named “Information.pdf.”**

Each PI must respond to the appropriate set(s) of questions if the proposed project involves human subjects. The RFI will be used for program planning purposes and will not be reviewed during scientific peer, military relevance, or programmatic review.

**Human subjects:**

- a. State at what point in time work with human subjects will begin (in agreement with the SOW).

- b.** Describe the recruitment process:
- Methods for identification of potential volunteers (e.g., medical record review, obtaining sampling lists, health care provider identification, etc.).
  - Description of compensation plan (should be fair and not provide undue inducement; if the study requires multiple visits, a plan for pro-rating payments in the event of volunteer withdrawal should be considered).
  - Type of consent to be used (informed, waived, or surrogate).
- c.** List the major inclusion and exclusion criteria of the study.
- d.** Provide the following information: The number of subjects that must be enrolled to properly power the proposed study, the number of subjects that must be screened to meet the enrollment target number, and the plan for replacing subjects who choose to drop out.

**Military subjects (if applicable):** Describe plans for military populations use for the proposed research project. Provide the following information.

- a.** Discuss why a civilian population cannot provide an appropriate assessment for the proposed research study.
- b.** Provide the name(s) of key personnel listed on this proposal who currently have access to the military population to be used for the proposed research study, if applicable.
- c.** Has an appropriate military population already been identified?  YES  NO  
If no, proceed to letter “d” below.  
If yes, provide the following information:
- Does the PI have a letter of support to access the population?  YES  NO
  - Does the PI need assistance getting a letter of support to access the population?  YES  NO
- d.** Does the PI need support from the CDMRP for identification of an appropriate military population and an appropriate recruitment strategy?  YES  NO
- e.** Check all boxes that apply for the Military service affiliation required:  
 US Army     US Marine Corps     US Navy     US Air Force  
 No preference
- f.** Check all boxes that apply for the type of military population required:  
 Active Duty     Reserves     National Guard     Retired     VA  
 No preference
- g.** Does the proposed research project require pre-deployment and/or post-deployment access to troops? Include a table, such as the one below (Table 3), indicating at what months during the period of performance for this award access to troops will be required.

**Table 3. Deployment-related table.**

<b>Deployment Phase</b>	<b><u>Start</u></b> (month during period of performance)	<b><u>End</u></b> (month during period of performance)
Pre-Deployment		
Deployment <sup>1</sup> - provide name of in-theater military investigator		
Post-Deployment		

<sup>1</sup>Research conducted using military populations in Iraq is conducted solely by select elements of the Multi-National Corps-Iraq (MNC-I). PIs outside of this system who submit a research proposal designed to recruit patients within MNC-I must be working in collaboration with an in-theater military investigator, undergo an in-theater review, and be approved by the MNC-I Command and the MNC-I designated Institutional Review Board. Given the constraints of wartime operations, investigators without an ongoing collaboration with an appropriate military investigator should strongly consider alternatives to conducting in-theater research. At present there is no ability to conduct research using military populations in Afghanistan.

**h.** Describe the study intervention. Briefly describe the data collection procedures and interaction(s) with the subjects, detailing how frequently and for what duration the investigator will interact with the subject (e.g., initial interview, followed by weekly psychological intervention session for 20 weeks). ***In a table, provide a flowchart of data points to be collected and indicate the timing within the performance period.***

**Attachment 6: Federal Agency Financial Plan (if applicable). No page limit, named “FedFin.pdf.”** Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2009, 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.

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

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

**NEW FOR FY08:** 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 3).

**Figure 3. Credential, e.g., agency login.**

Organization Name:  Division:   
\* Street1:  Street2:   
Organization Name:  Division:   
\* Street1:  Street2:   
\* City:  County:  \* State:  Province:   
\* Country:  \* Zip / Postal Code:   
\* Phone Number  Fax Number  \* E-Mail   
Credential, e.g., agency login:   
\* Project Role:  PD/PI  Other Project Role Category:

**PI Biographical Sketch: Four-page limit.** Suggested format is provided as in [Appendix 9](#). Name the PDF file as “Biosketch\_LastName.pdf” where “LastName” is the name of the PI. Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of this award.

#### 4. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. Refer to the Program Announcement/Funding Opportunity for limits on funding and period of performance.

*The program does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted. The maximum funding amount may be requested for less than the maximum performance period if addressed adequately in the Budget Justification.*

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.

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

- **Maximum Obligation:** The USAMRMC does not amend grants 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 Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31, Contract Cost Principles and Procedures (<http://farsite.hill.af.mil>).
- **Educational Institutions:** 2 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 Proposals:** The cost of preparing proposals 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.

**Section A & B – 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 proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K).

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 proposals for funding. For all personnel identified on the budget form, list the percentage of each appointment to be dedicated to this project.

**Section C – Equipment Description:** It is 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 for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than one 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 (Section K), to include:

- **Vendor Quote:** Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
- **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 contractor with contractor 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.

#### **Section D – Travel**

- **Travel costs to attend one scientific/technical meeting.** Costs should not exceed \$1,800 total for the performance period.
- **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 grant officer 30 days before travel, unless identified in the proposal that is part of the award.
- **Travel to CDMRP-required meetings.** Funds for the PI to attend one Department of Defense military research-related meeting to be determined by the CDMRP during the performance period. Justification must be provided if additional personnel are included in the travel budget. Costs should not exceed \$1,800 for travel to this meeting.

**Section E – Participant/Trainee Support Costs:** This section is self-explanatory; follow the instruction in the form.

#### **Section F – Other Direct Costs (as applicable)**

**Section F.1 – Materials and Supplies (Consumables):** The justification (to be included in Section K) supporting material and supply (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

**Section F.2 – Publication Costs:** This section is self-explanatory.

**Section F.3 – Consultant Services:** Regardless of whether funds are requested, the justification (to be included in Section K) should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

**Section F.4 – ADP/Computer Services:** This section is self-explanatory.

**Section F.5 – Subaward/Consortium/Contractual Costs:** On the project's Research and Related Budget Form, 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.

**Section F.6 – Equipment or Facility Rental/User Fees:** This section is self-explanatory.

**Section F.7 – Alterations and Renovations:** Not allowable.

**Sections F.8-F.10 – Additional Direct Costs (if applicable):**

**a. Research-Related Subject Costs:** Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

**b. Miscellaneous Costs:** Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified in Section K.

**Section G – Direct Costs:** This section is self-explanatory. All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

**Section H – Indirect Costs (overhead, general and administrative, 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 K) regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or CFR provisions. Commercial firms can also visit [www.dcaa.mil](http://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.

**Section I – Total Direct and Indirect Costs:** This section is self-explanatory.

**Section J – Fee:** A profit or fixed fee is not allowable on grants or cooperative agreements.

**Section K – Budget Justification:** The Budget Justification for the entire performance period must be attached as a PDF file named “Justification.pdf” to the Research & Related Budget – Section K (under budget period one). Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.

***NOTE: While the budget justification must include information for all budget periods, this file must be uploaded for budget period one before access will be granted to subsequent budget periods.***

## **5. 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.

## **6. R&R Subaward Budget Attachment(s) Form (optional form; use if applicable)**

Files attached to the R&R Subaward Budget Attachment(s) Form must be PureEdge documents. Extract an R&R Subaward Budget Attachment for each subaward, using the button provided on this form. Save each attachment to a computer and complete the form(s).

The Budget Justification for each subaward must be attached as a PDF file named “Justification\_LastName.pdf,” where “LastName” is the investigator of the subaward, to the Research & Related Budget – Section K for that subaward. Each subaward budget justification must include information for all budget periods. This file must be uploaded for budget period one before access will be granted to subsequent budget periods for the subaward. Once all subaward budget files are completed, attach all subaward budget file(s) for this application to the R&R Subaward Budget Attachment(s) Form.

The DUNS number for each subaward site should be included on this form.

A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. The following information must be provided on subawards:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;

- The proposed acquisition price; and
- The applicant's cost or price analysis for the subgrant or subcontract proposed price.

## 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:** 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 proposals from HBCU/MI. This provision is based on guidance from Executive Orders 12876, 12900, and 13021. Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement 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 proposal must 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:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** Must be 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 must 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 proposal 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 proposal 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 proposal 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

### COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Scientific peer and military relevance reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. ***Pre-applications or proposals missing required components as specified in the Program Announcement/ Funding Opportunity may be administratively rejected.***

***If the research is not relevant to currently advertised Deployment Related Medical Research Program (DRMRP) topic areas, the Government reserves the right to administratively withdraw the proposal.***

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget is missing.
- Fiscal Year 2008 (FY08) DRMRP Scientific Peer and/or Military Relevance Reviewer(s) have not declared a Conflict of Interest (COI) but are found to have involvement with the applicant prior to or during the review.
- FY08 Joint Senior Leadership Integration Panel (JSLIP) member(s) are named in the proposal.
- FY08 JSLIP member(s) are found to be involved in any capacity in the pre-application and proposal processes including but not limited to concept design, proposal development, budget preparation, and the development of any supporting document.
- FY08 JSLIP member(s) communicated program priorities prior to the deadline for proposal submission listed in this program announcement.

A list of the FY08 JSLIP members may be found at <http://cdmrp.army.mil>.

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for scientific peer review or military relevance review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for scientific peer review or military relevance review.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.

## APPENDIX 4

### GRANTS.GOV INSTRUCTIONS

#### A. Public Law 106-107

Proposals requesting funding from the Congressionally Directed Medical Research Programs (CDMRP) will be submitted through the Federal Government's single entry portal, [Grants.gov](https://www.grants.gov), in compliance with Public Law 106-107 (P.L. 106-107). 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 are 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 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 proposals submitted in response to the program announcement to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit proposals 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](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](https://www.dunandbradstreet.com)

(<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 proposal 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](http://www.dlis.dla.mil/Forms/Form_AC135.asp).

**3. AOR must be registered with Grants.gov:** Before submitting a proposal, 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 proposals 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 a proposal 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 CFR 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 proposal packet through his or 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 proposals.

#### C. Integrity of Review Process

The scientific peer review, military relevance review, and programmatic review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that proposal 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 proposal 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 proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity 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.

#### **D. Disclosure of Proprietary Information Included in a Proposal**

Proprietary information submitted in a proposal 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 proposal 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; proposals 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 or her proposal. 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 a proposal 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, 2009. 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. 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.

#### **I. 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.

#### **J. Contracted Fundamental Research**

Any awards under this PA 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.

## APPENDIX 6

### INSTRUCTIONS AND GUIDELINES 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](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/FY02FSPAppendix.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 proposal). 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/docs/rcq/ACUROAnimalAppendix.doc>). 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 proposal).

During the regulatory review process for research involving human subjects, the recommendations of the second tier 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 are reporting requirements and responsibilities of the Principal Investigator to the USAMRMC Office of Research Protections ORP, HRPO, and should be reflected in the protocol:

**1. Requirements:** 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.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at <https://mrmc.amedd.army.mil/rodorphrpo.asp>.

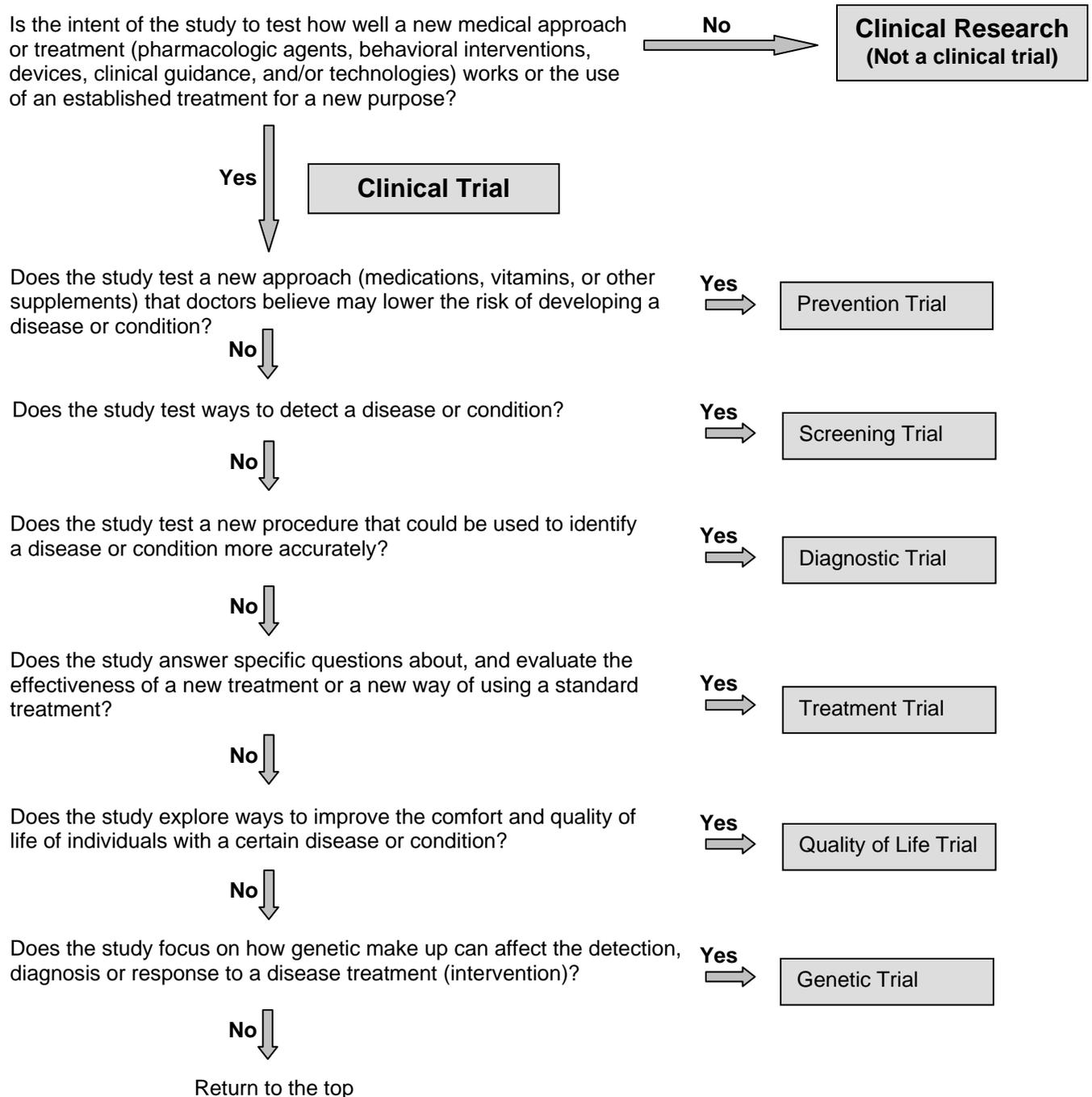
**2. Informed Consent Form:** Elements to include in the informed consent form can be found at <https://mrmc.amedd.army.mil/docs/rcq/GuidelinesForInvestigators.doc#p41SecF>, and an informed consent form template is located at [https://mrmc.amedd.army.mil/docs/rcq/consentform\\_template.pdf](https://mrmc.amedd.army.mil/docs/rcq/consentform_template.pdf).

**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.”

Furthermore, and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual’s legally authorized representative must be obtained before the individual’s participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, 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.

**4. Clinical Trial Registry:** PIs are required to register clinical trials individually on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: 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 the Human Research Protection Office (HRPO) and the local Institutional Review Board. 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.



## **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 proposal.

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 report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used 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
AOR.....	Authorized Organizational Representative
ARP.....	Autism Research Program
AVI.....	Audio Video Interleave
BCRP.....	Breast Cancer 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
GWVIRP.....	Gulf War Veterans' Illnesses 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
IRS.....	Internal Revenue Service
JPEG.....	Joint Photographic Experts Group
JPRP.....	Joint Programmatic Review Panel
JSLIP.....	Joint Senior Leadership Integration Panel

DOD Deployment Related Medical Research Program  
Hypothesis Development Award

LAR.....	Legally Authorized Representative
LOI.....	Letter of Intent
M.....	Million
MB.....	Megabyte
MNC-I.....	Multi-National Corps – Iraq
MPEG.....	Moving Picture Experts Group
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
PA.....	Program Announcement
PCRP.....	Prostate Cancer Research Program
PD.....	Project Director
PDF.....	Portable Document Format
PI.....	Principal Investigator
P.L.....	Public Law
POC.....	Point of Contact
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
TSCR.....	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) Form.**

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.