Application Instructions & General Information

Department of Defense Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Idea Award

Funding Opportunity Number: W81XWH-08-GWIRP-IDEA

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These instructions apply only to the mechanism listed above.

I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, 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

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

3. Grants.gov contacts: Questions related to submitting applications through the 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 about Grants.gov submissions.

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

Email: 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) 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 DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry 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).
- 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 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 after submission of the pre-application, the PI must contact the CDMRP 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. 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 SF-424 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) Integration Panel (IP) 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 IP members may be found at http://cdmrp.army.mil/research

4. **Preproposal Narrative and Pre-Application Supporting Documentation:** The Preproposal Narrative and supporting documentation will be screened, and if selected, PIs will receive notification of invitation to submit a proposal. Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Preproposal Narrative, Pre-Application Supporting Documentation, and Pre-Application Screening Criteria.

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

Proposals will not be accepted unless a PI has been invited. Do not submit a proposal unless the PI receives a letter of invitation.

The PI will be assigned a unique and separate proposal log number by the CDMRP eReceipt system. The PI must submit his or her Grants.gov application package using his or her unique log number. Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

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 CDMRP eReceipt help desk at help@cdmrp.org or 301-682-5507.

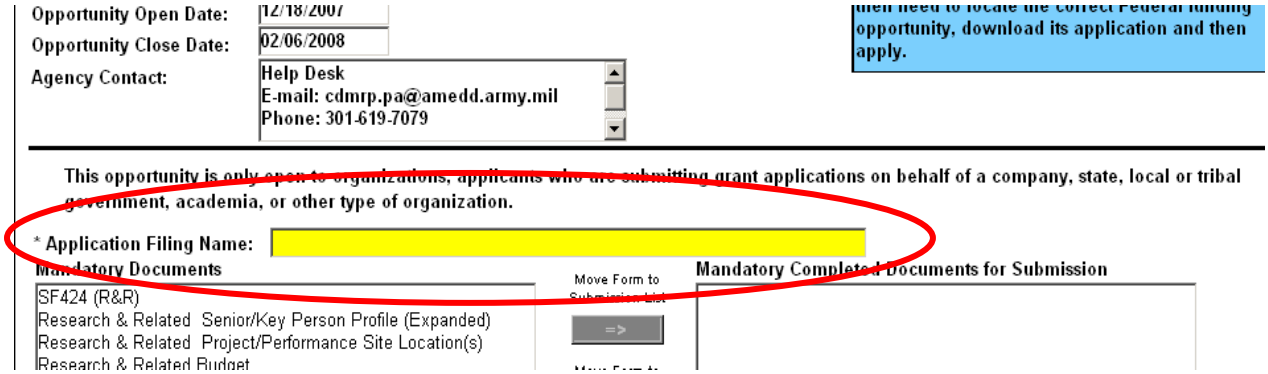
Submission of a proposal through Grants.gov has several institutional requirements, which may take several weeks to complete.

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) for the specific funding opportunity.

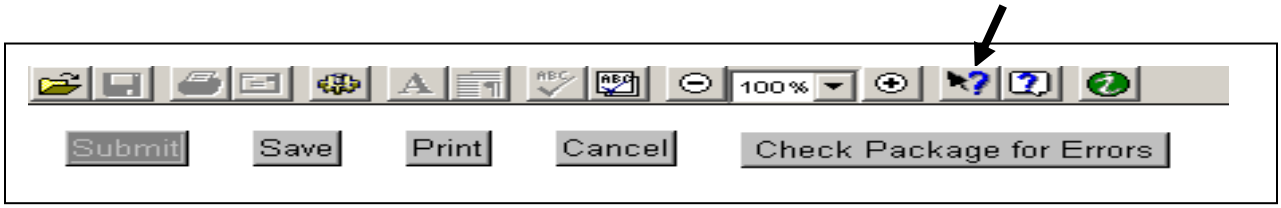
First, fill in the **Application Filing Name** on the first screen of the Grant Application Package using the **CDMRP log number** acquired during the pre-application process. *Do not fill in the Competition ID.*



The following table 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.

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 and Public Abstracts	Upload as Attachment 3 (Abstracts.pdf)
	Statement of Work	Upload as Attachment 4 (SOW.pdf)
	Innovation Statement	Upload as Attachment 5 (Innovation.pdf)
	Impact Statement	Upload as Attachment 6 (Impact.pdf)
	Use of Hazardous Chemical or Biological Agents (if applicable)	Upload as Attachment 7 (Hazard.pdf)
	Federal Agency Financial Plan (if applicable)	Upload as Attachment 8 (FedFin.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 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.



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 Federal Identifier 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/Principal Investigator (PD/PI).
- **Block 6 – Employer Identification.** Enter the EIN (Employer Identification Number) or TIN (Tax Identification Number) 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 Representative.** 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. **Paper 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 information regarding content of the Project Narrative, page limits, 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 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: 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 used.

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 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: ***NEW FOR FY08:*** 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). 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 institutional 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 that the PI has the resources necessary for the proposed work.

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 and Public Abstracts: Single PDF file named "Abstracts.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 in either the technical or the public abstract.

Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed in either abstract.

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.
- Innovation: Briefly describe how the proposed project uses innovation to advance the prevention, detection, diagnosis, and/or treatment of Gulf War Illness.
- Impact: Briefly describe how the proposed project will have an impact on improving the health and lives of veterans with Gulf War Illness.

Public Abstract: One-page limit. Start on a new page. The public abstract is an important component of the proposal review process because it addresses issues of particular interest to the consumer advocate community.

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposal.
  - 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 GWI research?

Attachment 4: Statement of Work (SOW): Two-page limit, named "SOW.pdf". The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include aims to be funded by this proposal. The SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Include the following information for each study site/subcontract site (collaborative site and consultant) that will be actively participating in the study:
  - Institution name

    - Institution address
    - Collaborator, consultant, and/or subawardee name
    - Animal or human studies at this site
- Identify the timeline and milestones for the work over the period of performance for 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 if the work involves animal, human subjects, or anatomical samples.
- Note the number of research subjects (animal or human) and/or anatomical samples required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

Attachment 5: Innovation Statement: One-page limit. Named "Innovation.pdf". Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Innovation Statement. The Innovation Statement will be available for both peer review and programmatic review.

Attachment 6: Impact Statement: 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.

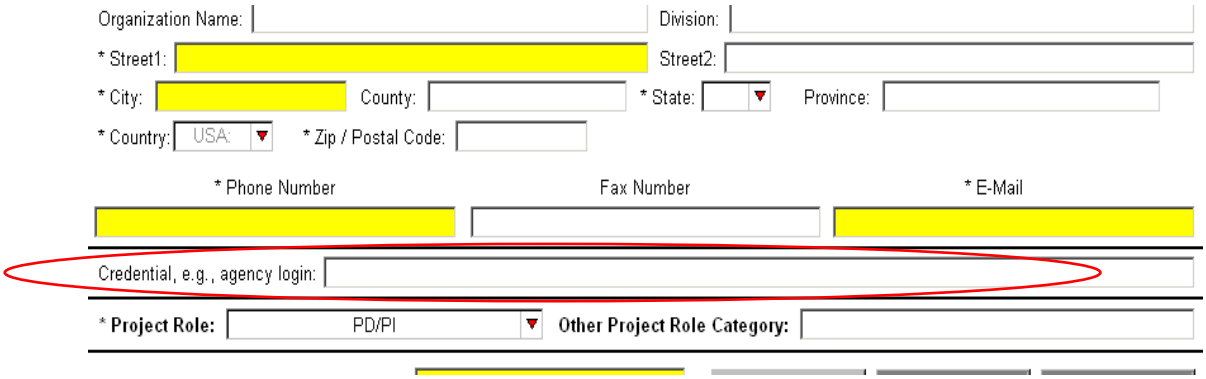
Attachment 7: **Use of Hazardous Chemical or Biological Agents (if applicable): No page limit. Named "Hazard.pdf".** The applicant must submit a plan for acquiring, using and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as Centers for Disease Control and Prevention (CDC) registration, an approved institutional safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate also if agents used are purchased commercially, and if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

Attachment 8: 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".



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.

Proposals 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 of the individual. Refer to content requirements under "PI Current/Pending Support" listed above.

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 period of performance 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:

- **Subcontracting Indirect Costs:** When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.
- **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 DOD 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 (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 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 US Army Medical Research Acquisition Activity 30 days before travel unless identified in the proposal that is part of the award.
- **Travel to CDMRP-required meetings** (if applicable). Costs should be reasonable.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

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. When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.

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 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 to subsequent budget periods will be allowed.

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 locally 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 to subsequent budget periods for the subaward will be allowed. 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 totaling $10,000 or more:

- 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; and
- The proposed acquisition price.
- The applicant's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $550,000 and the applicant is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the applicant is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7 (http://farsite.hill.af.mil). A mutually agreeable plan will be incorporated as part of the resultant contract.

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 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.

Duplicate Submissions: 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.

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, PIs 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. Peer 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.**

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 and/or budget justification are missing.
- Fiscal Year 2008 (FY08) Integration Panel (IP) members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP 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 peer review.

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

Proposals that appear to include plagiarized information will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the 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, 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 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 US Army Medical Research and Materiel Command requires proposals submitted in response to the program announcements 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 the PI's organization conducts business with the Federal Government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a DUNS number or registration in 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. **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 in place, 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.

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. Authorized Organizational Representative (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. 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.

C. Award Notices

Each PI will receive notification of the award status of his or her proposal. A copy of the peer review summary statement, if applicable, will be posted to the Congressionally Directed Medical Research Programs (CDMRP) eReceipt system. PIs can expect to receive this notification approximately 4 weeks after programmatic review.

D. 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.

E. 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 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.

F. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. 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 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 US Public Law 110-85.

G. 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.

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.

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/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 (formerly Regulatory Compliance and Quality), 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 consdiered 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 consdiered 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 resposibilities of the PI to the USAMRMC's Office of Research Protections, 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.

3. Intent to Benefit: PIs 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. 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 (PI) 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.**

Report requirements include the following:

1. **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.

2. **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.

3. **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.

4. **Animal Use Reports.** PIs 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
CDC .....Centers for Disease Control and Prevention
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
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
LAR .....Legally Authorized Representative
LOI .....Letter of Intent
M .....Million
MB .....Megabyte

MPEG .....Moving Picture Experts Group
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
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
WAV .....Waveform Audio

APPENDIX 9

Forms

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 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 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.