

**Program Announcement**

**Department of Defense (DOD) Post-Traumatic Stress Disorder  
and Traumatic Brain Injury (PTSD/TBI) Research Program**

**Supplement to the U.S. Army Medical Research and Materiel Command (USAMRMC)  
Broad Agency Announcement (BAA) 06-1**

*All guidelines contained in this FY07 Supplement supersede BAA 06-1 instructions*

**Funding Opportunity Number: W81XWH-07-TBI-IIRA**

**TBI Investigator-Initiated Research Award**

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## I. HELPFUL INFORMATION

### A. Agency Name

US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

### B. Agency Contact(s)

**1. BAA Supplement, proposal format, or required documentation:** Principal Investigators (PIs) and Authorized Organizational Representatives (AORs) should submit questions as early as possible. However, 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:** A help line for questions relating to the submission of pre-application components through the CDMRP eReceipt system is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. However, response times will vary depending upon the volume of inquiries. Help also is available on the CDMRP website or by email as follows:

Website: <https://cdmrp.org>  
Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**3. Grants.gov:** Issues in submitting applications through the [Grants.gov](https://www.grants.gov) (<http://www.grants.gov>) portal should be directed to Grants.gov at 800-518-4726 or email [support@grants.gov](mailto:support@grants.gov). The Grants.gov hours of operation are Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time. Deadlines for proposal submission are set at 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 to assist with Grants.gov submissions. Please plan ahead accordingly, as the CDMRP Help Desk is not able to answer questions about Grants.gov submissions.

***Grants.gov will only notify the PI of changes made to this BAA Supplement and/or Application Package 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. Please note that 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 by Grants.gov.***

### **C. Anticipated Instrument Type(s)**

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request via:

Fax: 301-619-2937  
Email: [qa.baa@amedd.army.mil](mailto:qa.baa@amedd.army.mil)

### **D. Catalog of Federal Domestic Assistance (CFDA) Number 12.420**

Military Medical Research and Development.

### **E. Commonly Made Mistakes**

- Pre-application submission is not completed before the mandatory pre-application deadline (pre-application remains in draft status).
- Failure to request updates on any modifications made to the application package.
- Incorrect application package or award mechanism is used to submit a proposal through Grants.gov.
- Attachments are uploaded into the incorrect form on Grants.gov.
- Files are attached in the wrong location on Grants.gov forms.
- Attachments are not PDF documents.
- Page limitations are exceeded.
- DUNS number is not confirmed well before the proposal deadline.
- Responses by Grants.gov helpdesk may not occur in time for the proposal deadline.
- Failure to submit proposal by receipt deadline.

### **F. Grant Writing**

The USAMRMC offers Grant Writing technical assistance through a tutorial titled “Writing Competitive Proposals”. The tutorial can be accessed at <http://www.mrmc.smallbusopps.army.mil/tutorial/index.htm>; select Writing Competitive Proposals.

## II. FUNDING OPPORTUNITY DESCRIPTION

Funding of proposals received in response to this BAA supplement is contingent on the availability of Federal funds appropriated in a bill for this program.

### A. Award Description

The Traumatic Brain Injury (TBI) Investigator-Initiated Research Award supports basic and clinically oriented research that will (1) result in substantial improvements over today's approach to the treatment and clinical management of TBI, (2) facilitate the development of novel preventive measures, and (3) enhance the quality of life of persons with TBI. Proposals must include ***preliminary and/or published data*** relevant to TBI research and the proposed project. Preliminary data is unpublished data. If the preliminary and/or published data is generated from a source other than the applicant, appropriate acknowledgement is required. For example, if the preliminary data has been generated by a colleague, acknowledgement should be made by listing the investigator's name, institution, and a statement that the data has been obtained via personal communication. Describe previous experience most pertinent to this proposal. Cite relevant literature references for published data. Proposals containing clinical trials or clinical research are appropriate for this award.

It is envisioned that access to Active Duty, National Guard, Reserve troops, and/or Military patient populations will be coordinated through a centralized DOD coordinating office, to be established prior to final recommendation of proposals for funding. Those proposals that score favorably during the scientific peer review and require access to Military patient populations will be forwarded to the centralized DOD coordinating office for consideration and review for availability and access to military patient populations prior to being recommended for funding. ***Please do not contact any Commander of Active duty, National Guard, Reserve troops and/or Military patient populations at this time or during preparation of your proposal submission. However we highly encourage you to collaborate with military researchers and clinicians. Access to Military populations will be handled by the coordinating center only. If selected for funding you will be provided guidance on how to obtain access to the appropriate population.***

Submissions that propose to recruit patients from Department of Veterans Affairs (VA) Medical Centers or use information from VA data systems must include an investigator with a VA appointment. This individual may be the principal investigator for the entire proposal or a VA collaborator willing to assume the role of principal VA investigator for the VA component of the proposal.

Currently, there is a very limited ability to conduct human research in the CENTCOM Area of Responsibility. At present, this capability exists solely within select elements of the Multi-National Corps Iraq (MNC-I). There is no ability to conduct human research in Afghanistan at present. All research conducted within MNC-I must be in collaboration with an in theatre military investigator, undergo an in theatre 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 a military investigator should strongly consider alternatives to the conduct of research in the wartime theatre. Note: DOD-supported human subjects research can only be conducted by institutions (to include those in

theatre) with approved Federal Assurances of Compliance from Human Research Protection. It is strongly suggested that PTSD and TBI research involve civilian and non-deployed military trauma populations.

The Fiscal Year 2007 (FY07) TBI or PTSD Investigator-Initiated Research Award Mechanism encourages proposals that specifically address one or more of the following research gaps:

1. Treatment and Clinical Management of TBI such as (but not limited to):
  - Development and implementation of a TBI clinical trials network to test new therapeutic interventions and assess advanced diagnostic and monitoring technologies (imaging, proteomics, and others) with longterm outcomes.
  - Development of standardized diagnostic criteria that captures the dynamic nature of the injury.
  - Development of standardized clinical management procedures.
2. Neuroprotection and repair strategy research such as (but not limited to):
  - Development of new and improved animal models for blast injury, mild TBI and poly-trauma with TBI, and
  - Advance the understanding of pathophysiology leading to the development of new therapeutic interventions in preclinical models.
  - Advance the understanding of threshold of injury, role of repeated exposure, and identification of individual factors that may allow for risk stratification.
  - Research into neuron repair (e.g., regeneration, cell transplantation, etc.).
  - Research into the prevention of injury through protective equipment, prophylactic drugs, other agents, change in behavior, or education.
3. Rehabilitation/Reintegration Strategies such as (but not limited to):
  - Development of a clinical research network that may assess short and long term outcomes in medical, vocational, interpersonal and psychosocial arenas.
  - Research into the short and long term treatment of associated conditions, such as cognitive deficits, depression, substance abuse, PTSD and epilepsy.
  - Research into educational tools for affected military members, units, leaders, families, providers and communities.
  - Standardizing return to duty criteria.
  - Family and Community re-integration.
  - Research into neural plasticity, physical therapy, or neural prostheses (such as brain-computer interfaces).
4. Field Epidemiology of TBI (with emphasis on mild TBI) such as (but not limited to):

- Determination of baseline and periodic neuropsychological assessments with certification of validation and reliability in the various groups at risk of TBI.
- Determination of the incidence of mild TBI and trajectory of symptoms among military relevant populations.
- Determination of factors critical to non-subjective diagnosis of mild TBI and PTSD differentiation.
- Comprehensive evaluation brain pathology from theater injuries, with an emphasis on linking the relevant factors of the specific mechanism of injury, personal protective equipment (PPE), individual factors (gender, age, genetics, environmental and other), and the effect of medical interventions.

5. Physics of Blast as it Relates to Brain Injury such as (but not limited to):

- Sensors to quantify and methods to analyze the degree of personnel exposure to blast events(s) (e.g., shockwave, pressure, acceleration, or other injury producing parameters of blast exposure).
- Generation of blast injury models which define the causal mechanisms for TBI in sufficient detail to enable its prevention and mitigation.
- Development of models, algorithms, or devices which characterize or quantify those aspects of blast (e.g., peak pressure, duration, pressure gradient, impulse, etc.) that may contribute to TBI.
- Models to measure both the incident and cumulative blast parameters most responsible for brain injury, such as dosimeters, clinical algorithms, or other means.
- Evaluation of the clinical relevance of field data generated by sensors, including accelerometers and dosimeters.

*It is the responsibility of the PI to clearly and explicitly articulate the project's innovation, its relevance to the above research gap areas, and the impact it may have on the field of traumatic brain injury research.*

**Multiple PI Option:** The FY07 TBI Investigator-Initiated Research Award supports collaborative research between academia, Historically Black Colleges and Universities/Minority Institutions, industry, the military Services, the Department of Veterans Affairs (VA), and other Federal Government agencies in order to bring a new perspective to TBI research and/or facilitate progress in the field by combined effort. Therefore, up to three investigators may work on a single project, each of which will be recognized as a PI and receive a separate award. **One member of the team will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with the proposal. The other member(s) will be referred to as the Partnering PI(s).** *All the investigators must collaborate to submit a single proposal addressing a central problem or question in TBI research.* It should be clear that all investigators have an equal level of intellectual input and effort. Multidisciplinary and multi-institutional projects are allowed. If the project is multi-institutional, PIs should include plans for communication between investigators at each institution. Additionally, participating institutions must be willing to resolve potential intellectual and material property issues and to

remove any barriers that might interfere with achieving high levels of cooperation to ensure successful completion of this award.

## **B. Eligibility**

Independent investigators at or above the level of Assistant Professor (or equivalent) with access to appropriate research facilities are eligible to submit proposals. Additional information about individual and institutional eligibility may be found in [Appendix 1](#). In the case of multiple PIs, one member of the team will be identified as the Initiating PI, who will be responsible for the majority of the administrative tasks associated with the proposal. The other member(s) will be referred to as the Partnering PI(s). *If the proposal contains a single PI, he/she will be referred to as the Initiating PI hereafter.*

## **C. Funding**

It is anticipated that a separate award will be made to each PI's institution. The combined total funding for all institutions can be requested for up to \$600,000 for direct costs for up to a 4-year performance period plus indirect costs as appropriate. If there is more than one PI, all PIs are expected to be equal partners in the research and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified. When an applicant institution calculates its own indirect costs for subawards, it can only charge indirect costs on the first \$25,000 of each subaward.

For proposals incorporating clinical trials or clinical research, the combined total funding for all institutions can be requested for up to \$1.5M for direct costs for up to a 4-year performance period plus indirect costs as appropriate. However, such a request must be accompanied by a compelling justification.

Funds can cover:

- salary
- research supplies
- equipment
- consultation with scientific and/or technical experts (e.g., statisticians, editors)
- clinical costs
- travel to scientific/technical meetings
- travel between collaborating institutions

The nature of the PTSD/TBI Research Program does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted.

*The CDMRP expects to allot approximately \$5 million (M) of the \$150M FY07 TBI appropriation to fund approximately 8 Investigator-Initiated Research Award proposals, depending on the quality and number of proposals received.*



## **D. Award Administration**

Changes in PI, institution, and/or Statement of Work will only be allowed in extenuating circumstances and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

Transferring an award that includes a clinical trial will not be permitted.

## **E. Timeline for Submission and Review**

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) proposal submission.

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time, September 4, 2007
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, October 11, 2007
- **Peer Review:** December 2007
- **Programmatic Review:** January 2008

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2008.

*Please note that Grants.gov may take at least 48 hours to process your proposal submission and to notify you of any errors. It is strongly recommended that you submit your application as early as possible to allow sufficient time for error correction*

*You may be able to submit a proposal to [Grants.gov](http://Grants.gov) after the deadline and you will receive a message that your application is being processed. You will, however, receive notification at a later date that your proposal was late and will not be accepted by Grants.gov.*

### **III. PROGRAM HISTORY AND OBJECTIVES**

The PTSD/TBI Research Program was established in FY07 to promote research that will advance the prevention, detection, diagnosis, and treatment of military-relevant PTSD and TBI. The Program focuses its funding on innovative projects that have the potential to make a significant impact on improving the function, wellness, and overall quality of life for military Service members as well as their caregivers, families, and the American Public.

The FY07 PTSD/TBI Research Program challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the fields of military-relevant PTSD- and TBI-focused research. Proposals from investigators within the military Services and proposals involving multidisciplinary collaborations among academia, industry, the military Services, the Department of Veterans Affairs, and other Federal Government agencies are highly encouraged. Though the Program supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

The FY07 TBI appropriation is \$150M. The TBI Investigator-Initiated Research Award mechanism is being offered for the first time in FY07.

#### IV. SUBMISSION PROCESS STEP 1: PRE-APPLICATION SUBMISSION

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

To foster collaborations and to optimize partnerships, the Investigator-Initiated Research Award is structured to accommodate up to three PIs. The Initiating PI is responsible for completing the pre-application process and for ensuring that all requirements of the proposal submission process are met. Initiating and Partnering PIs, if applicable, each have different proposal submission requirements. Each PI must complete his or her respective proposal submission requirements.

Please note that each PI is equally responsible for the conduct and success of the project.

This section describes the process for pre-application submission. For proposal submission, see [Section V](#). ***Proposal submission will not be accepted unless a pre-application was previously submitted.*** The PIs and Organizations 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, please contact the eReceipt helpdesk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

*For assistance, please see Helpful Information ([Section I](#)).*

##### A. Pre-application Components and Submission

The pre-application for an Investigator-Initiated Research Award consists of a Letter of Intent (LOI) Narrative and the other components discussed below. This subsection provides a summary of the pre-application submission requirements.

All pre-application components for the TBI Investigator-Initiated Research Award mechanism, including the LOI Narrative, must be submitted electronically through the [CDMRP eReceipt system](#) by the **5:00 p.m. Eastern time, September 4, 2007 deadline**. 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.

- 1. Proposal Information:** The Initiating PI must enter the Proposal Information as described in the [CDMRP eReceipt system](#) before uploading the LOI Narrative.
- 2. Proposal Contacts:** Enter contact information for the Initiating PI and AOR. The contact information for the Partnering PI(s), if applicable, must be entered under the Collaborators and Conflicts of Interest tab.
- 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 for each PI. The Initiating PI must enter the name, email, and title of the Partnering PI(s), if applicable, and choose “Partnering

PI” from the drop-down list to indicate his or her role in the project. Add all individuals outside of the proposal who may have a conflict of interest in the review of this proposal and choose “COI” from the drop-down list to indicate a conflict of interest. Inclusion of FY07 PTSD/TBI Research Program Joint Program Integration Panel (JPIP) members in any capacity in the proposal, budgets, or any supporting document is considered a conflict of interest and will result in administrative withdrawal of the proposal. A list of the FY07 PTSD/TBI Research Program JPIP members may be found at <http://cdmrp.army.mil/prmrp/default>

**4. LOI Narrative:** The LOI Narrative has a *one-page limit* inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The LOI Narrative should be a brief description of the research to be conducted.

The LOI Narrative will be administratively reviewed prior to peer review; it will not be reviewed during peer and programmatic reviews.

**5. Formatting Guidelines and Submission:** The LOI Narrative must be a PDF file, in accordance with the [formatting guidelines](#) specified in [Appendix 4](#), and uploaded under the “Required Files” tab of the [CDMRP eReceipt system](#).

**6. PI Responsibilities:**

**a. Initiating PI Responsibility:** The Initiating PI is responsible for uploading the LOI Narrative (one-page limit) as a PDF file under the “Required Files” tab of the [CDMRP eReceipt system](#). The electronic PDF file uploaded in the [CDMRP eReceipt system](#) is the official pre-application submission file. After conversion of word processing documents to PDF files and before electronic submission, the Initiating PI should review his or her files to ensure that the pre-application complies with the [formatting guidelines](#).

Once the Initiating PI has completed the pre-application submission process, the eReceipt system will generate individual pre-application files for the Initiating and Partnering PIs. The [CDMRP eReceipt system](#) will notify the Partnering PI(s) with directions on how to obtain their files. The Initiating PI should download the pre-application file (in XML format) and attach it to form SF424 in Block 20 (pre-application) as part of the proposal submission through Grants.gov. Do not convert this file.

**b. Partnering PI(s) Responsibility (if applicable):** The Partnering PI(s) have no responsibilities in the pre-application process. However, once the Initiating PI has completed the pre-application submission process, the eReceipt system will generate a pre-application file for the Partnering PI(s). The Partnering PI(s) should download the pre-application file (in XML format) and attach it to Form SF-424 in Block 20 (pre-application) as part of the proposal submission through Grants.gov. Do not convert this file.

**7. AOR Approval:** The pre-application does not require approval by the AOR before submission. Please see [Appendix 2](#) for the definition of an AOR.

## V. SUBMISSION PROCESS STEP 2: PROPOSAL SUBMISSION

This section describes the process for submission of a proposal, once a pre-application has been submitted. Proposals must be submitted electronically by the AOR through Grants.gov ([www.grants.gov](http://www.grants.gov)). No paper copies will be accepted.

***Proposal submission will not be accepted unless a pre-application was previously submitted.***

The PIs and Organizations 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, please contact the eReceipt helpdesk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

***For complete information regarding forms and submission components, as well as general proposal preparation and submission instructions, please see [Appendix 3](#).***

Please note, submission of a proposal requires institutional registration with the Central Contractor Registry (CCR; see [Appendix 2](#)). Plan accordingly and allow several weeks for these registration processes. Grants.gov will not allow proposals to be submitted unless all of the registration steps have been completed.

***For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. Each PI must submit an individualized SF-424 (R&R) Application for Federal Assistance Form, Attachments Form, Research & Related Budget Form, Research & Related Project/Performance Site Location(s) Form, and R&R Subaward Budget Attachment(s) Form (if applicable). Each PI must also submit an identical copy of a joint Statement of Work (SOW).***

### A. Proposal Components Summary for the Initiating PI

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in [www.grants.gov](http://www.grants.gov) for the US Army Medical Research Acquisition Activity (USAMRAA) BAA supplement. The package includes:

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

- Pre-application file downloaded from the CDMRP eReceipt system

#### 2. Attachments Form

- Attachment 1: Project Narrative (15-page limit)
- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts

- Letters of Institutional Support
  - Letters of Collaboration (if applicable)
  - Attachment 3: Technical and Public Abstracts
  - Attachment 4: SOW
  - Attachment 5: Innovation Statement
  - Attachment 6: Impact Statement
  - Attachment 7: Federal Entity Financial Plan (if applicable)
- 3. Research & Related Senior/Key Person Profile (Expanded Form)**
- PI Biographical Sketch (four-page limit)
  - PI Current/Pending Support
  - Key Personnel Biographical Sketches (four-page limit each)
  - Key Personnel Current/Pending Support
- 4. Research & Related Budget Form**
- Budget Justification
- 5. Research & Related Project/Performance Site Location(s) Form**
- 6. R&R Subaward Budget Attachment(s) Form (if applicable)**

**B. Proposal Components Summary for the Partnering PI(s), If Applicable**

The proposal submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov. In order to complete the proposal submission process, the Partnering PI(s) must first obtain a pre-application XML file (do not convert to PDF) from eReceipt. Directions for downloading this file will be contained in an email from eReceipt. The package includes:

- 1. SF-424 (R&R) Application for Federal Assistance Form**
  - Pre-application file downloaded from the [CDMRP eReceipt system](#)
- 2. Attachments Form**
  - Attachment 4: SOW
  - Attachment 7: Federal Entity Financial Plan (if applicable)
- 3. Research & Related Budget Form**
  - Budget Justification
- 4. Research & Related Project/Performance Site Location(s) Form**

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

*Grants.gov will only notify the PI of changes made to this BAA Supplement and/or Application Package 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. Please note that 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 by Grants.gov.*

## VI. PROPOSAL REVIEW INFORMATION

### A. Proposal Review and Selection Overview

All proposals are evaluated by scientists and clinicians using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and program review processes must be conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and principal investigators 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.

Proposals that include plagiarized information will be administratively withdrawn. The institution will subsequently be requested to perform an investigation and provide those findings to the cognizant Grants Officer for a determination of the disposition of the application.

Violations by panelists or principle investigators that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

### B. Review Criteria

**1. Peer Review:** All proposals will be evaluated according to the following criteria, which are in order of descending importance:

- **Impact**
  - How the project addresses a critical problem in traumatic brain injury research.
  - How the project makes an original and important contribution to the goal of advancing research on the prevention, detection, diagnosis, treatment, or management of traumatic brain injury or enhancing the quality of life of affected individuals, families, and/or caregivers.
  - The difference this proposal will make, if successful, on traumatic brain injury research or patient care.



- **Research Strategy (preliminary and/or published data are required)**
  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary and or published data, and logical reasoning.
  - How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed.
  - How well the applicant acknowledges potential problems and addresses alternative approaches.
- **Innovation**
  - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
  - How the proposed research represents more than a mere extension or an incremental advance upon published data.
  - How the potential gain justifies the perceived risk.
- **Personnel**
  - Whether the PI(s) meets the eligibility requirements.
  - The appropriateness of the research team's background and expertise with respect to its ability to perform the proposed work, to include human subjects research.
  - The appropriateness of the levels of effort for successful conduct of the proposed work.
- **Environment**
  - The appropriateness of the scientific environment for the proposed research
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support, to include support for conducting human subjects research as applicable.
- **Budget**
  - How the budget is or budgets are appropriate for the proposed research.

**2. Programmatic Review:** Criteria used by the JPIP to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Military relevance,
- Programmatic relevance,
- Relative innovation and impact,

- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by the JPIP and recommended for funding to the Commanding General, USAMRMC.

## VII. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Failure to adhere to [formatting guidelines](#) ([Appendix 4](#)) makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection. *Proposals missing required components of the grants.gov application package (see [Section V](#)) may be administratively rejected.*

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

- Project Narrative exceeds page limit.
- Font size is less than 12 point.
- Margins are less than specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Page size greater than specified in the formatting guidelines.
- FY07 PTSD/TBI JPIP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY07 PTSD/TBI JPIP members may be found at <http://cdmrp.army.mil/prmrp/default>

For any other sections of the 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.

## VIII. APPENDICES

### 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.)

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

**Eligible Institutions:** USAMRMC makes awards to institutions; eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, Historically Black Colleges and Universities/Minority Institutions (HBCU/MI), hospitals, laboratories, and companies.

**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 BAA supplement 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

### GRANTS.GOV INSTRUCTIONS

#### A. Public Law 106-107

Proposals requesting funding from the 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 USAMRMC requires proposals submitted in response to the BAA supplement 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 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 you do business with the Federal Government on a continuing basis, it is likely you have already completed some of the actions, 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](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 (D&B) (<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 – please verify the status of your organization's CCR registration well in advance of the proposal submission deadline.***

You can 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. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization. Allow a minimum of 5 business days to complete the entire CCR registration. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service (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. 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 3

### INFORMATION FOR PROPOSAL SUBMISSION

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). This section describes the process for proposal submission. For pre-application submission, see [Section IV](#). Proposal submission will not be accepted unless a pre-application was previously submitted. This appendix outlines how to prepare a proposal application for submission through Grants.gov.

Each submission must include the completed package of forms identified in [www.grants.gov](http://www.grants.gov) for the US Army Medical Research Acquisition Activity (USAMRAA) BAA Supplement. The submission of specific documents will depend upon the award mechanism for which this proposal is being submitted, as specified in [Section V](#) and described below. All attachments must be uploaded as a PDF file in accordance with the [formatting guidelines](#) except for the pre-application XML file.

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.***

Click on “Help Mode” (see arrow in Figure 1 below) in the PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in this application package.

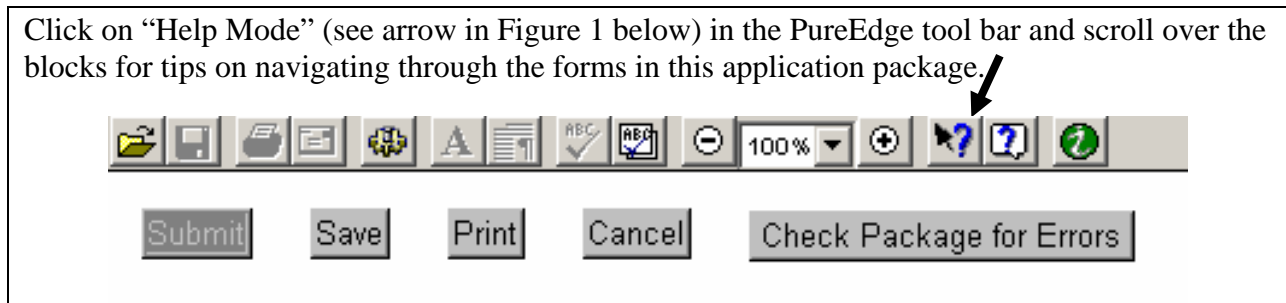


Figure 1: Grants.gov Application PureEdge Toolbar

#### A. Proposal Submission Components for the Initiating PI

For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. The Initiating PI must submit individualized forms identified in the table below. The Research & Related Senior/Key Person Profile (Expanded) Form must include information for the Partnering PI and all key personnel. The joint SOW attached to the Attachments Form must be an identical copy to that submitted by the Partnering PI.

<b>Form</b>	<b>Attachment</b>	<b>Action</b>
SF-424 (R&R) Application for Federal Assistance Form	Pre-application XML File	Enter the appropriate information in data fields
Attachments Form	Project Narrative (Narrative.pdf)	Upload as Attachment 1
	Supporting Documentation (Support.pdf)	Upload as Attachment 2
	Technical and Public Abstracts (Abstracts.pdf)	Upload as Attachment 3
	Statement of Work (SOW) (SOW.pdf)	Upload as Attachment 4
	Innovation Statement (Innovation.pdf)	Upload as Attachment 5
	Impact Statement (Impact.pdf)	Upload as Attachment 6
	Federal Entity Financial Plan (if applicable) (FedFin.pdf)	Upload as Attachment 7
Research & Related Senior/Key Person Profile (Expanded) Form	PI Biographical Sketch (Biosketch_LastName.pdf)	Attach to PI Biographical Sketch field
	PI Current/Pending Support (Support_LastName.pdf)	Attach to PI Current & Pending Support field
	Key Personnel Biographical Sketches (Biosketch_LastName.pdf)	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support (Support_LastName.pdf)	Attach to Current & Pending Support field for each senior/key person
Research & Related Budget Form	Budget Justification for entire performance period (Justification.pdf)	Attach to Section K in budget period one
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets and justifications (Justification_LastName.pdf)	Attach a separate budget with justification for each subaward

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 may be requested from the PIs. At that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the AOR.



## B. Proposal Submission Components for the Partnering PI

For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. The Partnering PI must submit individualized forms identified in the table below, with the exception that an identical copy of the joint SOW is uploaded through the Attachments Form.

<b>Form</b>	<b>Attachment</b>	<b>Action</b>
<b>SF-424 (R&amp;R) Application for Federal Assistance Form</b>	<b>Pre-application XML File</b>	<b>Enter the appropriate information in data fields</b>
<b>Attachments Form</b>	Project Narrative (Narrative.pdf)	Submitted by Initiating PI
	Supporting Documentation (Support.pdf)	Submitted by Initiating PI
	Technical and Public Abstracts (Abstracts.pdf)	Submitted by Initiating PI
	<b>Statement of Work (SOW) (SOW.pdf)</b>	<b>Upload as Attachment 4</b>
	Innovation Statement (Innovation.pdf)	Submitted by Initiating PI
	Impact Statement (Impact.pdf)	Submitted by Initiating PI
	<b>Federal Entity Financial Plan (if applicable) (FedFin.pdf)</b>	<b>Upload as Attachment 7</b>
<b>Research &amp; Related Budget Form</b>	<b>Budget Justification for entire performance period (Justification.pdf)</b>	<b>Attach to Section K in budget period one</b>
<b>Research &amp; Related Project/Performance Site Location(s) Form</b>		<b>Enter the appropriate information in data fields</b>
<b>R&amp;R Subaward Budget Attachment(s) Form (if applicable)</b>	<b>Individual subaward budgets and justifications (Justification_LastName.pdf)</b>	<b>Attach a separate budget with justification for each subaward</b>

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 may be requested from the PIs. At that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the AOR.

### C. 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 substantial changes that must be made after the original submission, the complete application package must be resubmitted. In these cases, the "Changed/Corrected Application" box must be checked and the Grants.gov tracking number must be entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable
- **Block 4 – Federal Identifier Box.** This box will be populated by Grants.gov for an original application, but the Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application) must be manually entered for changed or corrected applications.
- **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 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 19 – Authorized Representative.** 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** box and attachment should be used to attach the pre-application file associated with this proposal. This pre-application file must be downloaded from the CDMRP eReceipt system. *Please do not convert this XML file to PDF.*

### D. Attachments Form

The following information must be included as attachments to this form in accordance with the [formatting guidelines](#):

**Attachment 1: Project Narrative: Fifteen-page limit.** The Project Narrative is the main body of the proposal. The Project Narrative must be submitted by the Initiating PI as a single PDF file named "Narrative.pdf," in accordance with the [formatting guidelines](#).

Describe in detail how the proposed research is innovative and the impact it will have on traumatic brain injury. Presentation of preliminary or published data to support the rationale

for the proposed project is required. Preliminary data is unpublished data. If the preliminary and/or published data is generated from a source other than the applicant, appropriate acknowledgement is required. For example, if the preliminary data has been generated by a colleague, acknowledgement should be made by listing the investigator's name, institution, and a statement that the data has been obtained via personal communication. Describe previous experience most pertinent to this proposal. Cite relevant literature references for published data.

Describe the proposed project using the following outline:

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the projects' specific aims to be funded by this proposal.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

The 15-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.

**Attachment 2: Supporting Documentation.** Supporting Documentation is inclusive of information for each PI. The Initiating PI must upload Supporting Documentation as a single PDF file named "Support.pdf," in accordance with the [formatting guidelines](#).

- 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.
- Acronyms and Symbol Definitions: No page limit.** Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.
- Facilities & Other Resources: No page limit.** Describe the facilities available to each PI 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.
- Description of Existing Equipment: No page limit.** Include a description of existing equipment available to each PI to be used for the proposed research project.

**e. Publications and/or Patent Abstracts: Five-document limit per PI.** Include up to five relevant publication reprints and/or patent abstracts per PI. A patent abstract should provide a non-proprietary description of the patent application. Extra items will not be reviewed.

**f. Letters of Institutional Support:** 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 to each PI for this project. The letter should also indicate the extent to which each PI will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals.

**g. Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or institution.

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. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.***

**Attachment 3: Technical and Public Abstracts.** The technical and public abstracts must be submitted by the Initiating PI as a single PDF file named “Abstracts.pdf,” in accordance with the [formatting guidelines](#). 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.

**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.

- Describe the scientific objective and rationale for the proposal in a manner readily understandable by non-scientists.
  - 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 consumer-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study?

**Attachment 4: Statement of Work (SOW): Two-page limit.** The Initiating and Partnering PIs must create a joint SOW. For administrative purposes, an identical copy of the joint SOW must be submitted by each PI, uploaded as a single PDF file named “SOW.pdf” in accordance with the [formatting guidelines](#). 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 use at this site
- Identify the timeline and milestones for the work over the performance period 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 your 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;
- Indicate time required for human use approval and FDA submission of applicable documents (i.e., IND and IDE);
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

**Attachment 5: Innovation Statement: One-half-page limit.** The Innovation Statement must be submitted by the Initiating PI as a single PDF file named “Innovation.pdf,” in accordance with the [formatting guidelines](#). Summarize how the proposal is innovative. The

following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- Study concept - Investigation of a novel idea and/or research question.
- Research method or technology - Use of novel research methods or new technologies, including technology development, to address a research question.
- Clinical interventions - Use of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies - Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

Investigating the next logical step as an extension of previous work or incremental advancement on published data is not considered innovative.

*The Innovation Statement will be available for both peer and programmatic review.*

**Attachment 6: Impact Statement: One-half-page limit.** The Impact Statement must be submitted by the Initiating PI as a single PDF file named “Impact.pdf,” in accordance with the [formatting guidelines](#). State explicitly how the proposed work will have an impact on research or patient care. Describe how the combination of innovation and the expected results of the proposal will improve the function, wellness, and overall quality of life for Service members as well as their caregivers, families, and the American Public.

*The Impact Statement will be available for both peer and programmatic review.*

**Attachment 7: Federal Entity Financial Plan (if applicable).** Proposals from Federal entities must provide a plan delineating how all funds provided directly to them by USAMRAA will be obligated by September 30, 2008, 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.

A suggested plan would include having a foundation, non-Federal institution, or university act as the Awardee/Recipient of a Cooperative Agreement from USAMRAA. The Recipient may then provide personnel, equipment, and supplies (but not funds) to carry out the collaborative research. The Cooperative Agreement will define the relationship between the Government (to include the Federal entity) and the non-government entities.

The Federal Entity Financial Plan should be submitted as a single PDF file named “FedFin.pdf,” in accordance with the [formatting guidelines](#) by the proposal submission deadline. If the plan cannot be included with your proposal submission through grants.gov, The PI or Contract Representative should upload the plan as a PDF file under the "Regulatory and Other Documents" tab of the CDMRP eReceipt system by January 16, 2008. Failure to submit such a plan will result in proposal rejection prior to programmatic review.

## E. Research & Related Senior/Key Person Profile (Expanded Form)

*The Initiating PI must include the requested information for each senior/key person proposed on the project. Partnering PI information should be uploaded with Key Personnel information.* Each attachment must be a single PDF file, in accordance with the [formatting guidelines](#).

- 1. PI Biographical Sketch: Four-page limit.** Suggested format is provided as [Form 1](#). The biosketch must be saved as “Biosketch\_LastName.pdf” where “LastName” is the last name of the Initiating PI.
- 2. PI Current/Pending Support: No page limit.** Current/Pending Support for the Initiating PI must be submitted as a PDF file in accordance with the [formatting guidelines](#). This file must be named “Support\_LastName.pdf,” where “LastName” is the last name of the Initiating PI.

Proposals submitted under this BAA supplement should not duplicate other funded research projects.

*For all existing and pending research projects involving the Initiating PI 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.

**3. Key Personnel Biographical Sketches: Four-page limit per individual.** Suggested format is provided as [Form 1](#). Each biosketch must be saved as “Biosketch\_LastName.pdf” where “LastName” is the last name of the appropriate individual.

**4. Key Personnel Current/Pending Support: No page limit.** Current/Pending Support for each individual must be submitted as a PDF file in accordance with the [formatting guidelines](#). Each file must be named “Support\_LastName.pdf,” where “LastName” is the last name for the individual. Refer to “PI’s Current/Pending Support” above for content of this document, except substituting individual information for that of the Initiating PI.

## F. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. 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. ***Each PI must upload an individual budget and budget justification.***

The following cost regulations and principles must be adhered to 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 following regulations and principles:
  - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31 (<http://farsite.hill.af.mil>), Contract Cost Principles and Procedures.
  - **Educational Institutions:** OMB Circular A-21, Cost Principles for Educational Institutions.
  - **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.
  - **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments.
  - **Cost of Preparing Proposals:** The cost of preparing proposals in response to this BAA supplement 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 OMB Circulars A-21 and A-122.

**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).

The qualifications of each PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on 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 shall be separately negotiated.

An itemized list of 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 2 years 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 per year.** Costs should not exceed \$1,800.
- **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 USAMRAA 90 days before travel.

- **Travel to CDMRP-required meetings** (if applicable) ([Section II.C](#)). 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 – 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.

**Sections F.8–F.10 – Other Direct Costs (if applicable):** 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 OMB Circular 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. When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first \$25,000 of each subaward.

As a minimum, justification for indirect costs should identify:

- All individual cost elements included in each forecast rate;
- The basis used to prorate indirect expenses to cost pools, if any;
- How each rate was calculated; and
- 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. If a profit/fee is negotiated, a contract will be awarded. Any fixed fee applied to the research project must be listed and any claimed Facilities Capital Cost of Money supported by **DD Form 1861** ([www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html](http://www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html)) must be submitted with the proposal.

**Section K – Budget Justification:** The Budget Justification for the entire performance period must be attached by each PI 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.

*The budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods.*

#### **G. 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.

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

Please note that the files to be 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 your 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 you will be allowed to access 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 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 \$500,000 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. A mutually agreeable plan will be incorporated as part of the resultant contract.

## APPENDIX 4

### 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, except for the pre-application file (XML file) attached to block 20 of SF-424.
- **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:** Proposals 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 in the proposal 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.
- **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.

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

## APPENDIX 5

### AWARD ADMINISTRATION INFORMATION

#### A. Award Notices

Each Principal Investigator (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.

#### B. Administrative Requirements

Awards are made to organizations, not individuals. Each PI must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient 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 (OMB Circular A-110 and Department of Defense [DOD] Grant and Agreement Regulations) to be eligible for an award. Any organization requesting receipt of an award through this BAA supplement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at <http://www.ccr.gov>.

If allowed, a change in institutional affiliation will require the investigator 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 investigator'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.

#### C. Award Negotiation

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the US Army Medical Research Acquisition Activity (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 be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

#### D. Disclosure of Proprietary Information outside the Government

By submitting a proposal, each PI understands that proprietary information 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. Government Obligation**

PIs are cautioned that 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.

### **F. Information Service**

PIs may use the technical reference facilities of the National Technical Information Service ([www.ntis.gov](http://www.ntis.gov)), 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.

### **G. Inquiry Review Panel**

PIs may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and 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.

### **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. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

### **I. J-1 Visa Waiver**

It is the responsibility of the awardee 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

### REGULATORY REQUIREMENTS AND REVIEWS

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 may 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 may 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.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc>.

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; 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 “Research Involving Animals”, which can be found on the ACURO website <https://mrmc-www.army.mil/rodorpaurd.asp>). Allow 2 to 4 months for regulatory review and approval processes for animal studies. Specific requirements for research involving animals can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

#### **D. Research Involving Human Subjects, 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).

In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects or biological substances, a second tier of human subjects regulatory review and approval is required by the DOD, which is conducted by the USAMRMC ORP, Human Research Protection Office (HRPO). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. The recommendations of the second-tier HRPO review must be considered by the local IRB; therefore, to expedite the review of research involving human subjects, anatomical substances, and/or data, PIs should not submit documentation to their local IRB until they have received an initial review by HRPO.

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

**1. Requirements:** Specific requirements for research involving human subjects, anatomical substances, and/or data can be found at <https://mrmc.amedd.army.mil/rodorptoolkit.asp>.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction 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.detrick.army.mil/rodorphrpo.asp>.

**2. Informed Consent Form:** An informed consent form template is located at <https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc>.

**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. Investigators should be aware that this law makes placebo-controlled clinical studies 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:** Initiating 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 NIH database (see <http://prsinfo.clinicaltrials.gov/>, click on "Data Element Definitions," see section 6, "Study Phase" and "Study Type") including all Phase I-IV clinical trials and trials that do not fit into one or more phases, but that are clearly interventional or observational (e.g., some epidemiological or behavioral studies), are required to register.

**5. 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

### REPORTING REQUIREMENTS

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 award instrument. (Full US Army Medical Research and Materiel Command reporting 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.***

Reporting 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 reporting may be required as stipulated during award negotiations. Projects involving clinical studies will be required to submit quarterly reports outlining accrual and retention statistics and any problems with study execution. 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.** 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
ASDRP.....	Autism Spectrum Disorder 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
CMLRP.....	Chronic Myelogenous Leukemia Research Program
CR.....	Contract Representative
DFARS.....	Department of Defense Federal Acquisition Supplement
DOD.....	Department of Defense
DODGAR.....	Department of Defense Grant and Agreement Regulations
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
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  
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  
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  
XML.....Extensible Markup Language

**IX. CDMRP-SPECIFIC FORMS**

**FORM 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 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.