

Program Announcement

U. S. Army Medical Research and Materiel Command (USAMRMC)

Telemedicine and Advanced Technology Research Center (TATRC)

Vision Research Program (VRP)

Funding Opportunity Number:

W81XWH-09-TATRC-VRP

Table of Contents

I.	Helpful Information	3
	A. Contacts	3
	B. National Technical Information Service	3
	C. Commonly Made Mistakes	3
II.	Funding Opportunity Description	4
	A. Program History and Objectives	4
	B. Critical Areas	5
	C. TATRC Award Description	5
	D. Eligibility	6
	E. Funding	6
	F. Award Administration	7
III.	Timeline for Submission and Review	8
IV.	Submission Process and Application Instructions	8
	A. Pre-proposal Submission	8
	B. Full Proposal Components and Submission	9
	C. Formatting Guidelines	20
	D. Compliance Guidelines	21
V.	Information for Pre-proposal Review	22

A.	Pre-proposal Review	22
B.	Pre-proposal Review Criteria	22
VI.	Information for Full Proposal Review	22
A.	All Invited Full Proposals Review and Selection Overview	22
B.	Review Criteria	23
VII.	Grants.Gov Information	25
A.	Public Law 106-107	25
B.	Grants.Gov	25
VIII.	Administrative Information	26
A.	Excluded Parties List	26
B.	Administration Requirements	26
C.	J-1 Visa Waiver	26
D.	Disclosure of Information outside the Government	27
E.	Government Obligation	27
F.	Integrity of Review Process	27
G.	Disclosure of Proprietary Information Included in a Proposal	28
H.	Award Negotiation	28
I.	Title to Inventions and Patents	28
J.	Contracted Fundamental Research	28
IX.	Instructions and Guidelines for Regulatory Requirements	29
A.	Certificate of Environmental Compliance	29
B.	Research Involving Human Subjects or Human Data	29
X.	Instructions for Reports	33
A.	Research Progress Reports	33
B.	Fiscal Reports	33

I. Helpful Information

A. Contacts

To view all funding opportunities offered by the USAMRMC, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Questions related to the submission process for this announcement should be directed to Ms. Fay Peiffer at the U. S. Army Medical Research Acquisition Activity at 301 619-4055 or fay.peiffer@us.army.mil.

Questions related to the research area for this announcement should be directed to Mr. Robert Read at 301-619-4207 or Robert.Read@tatrc.org.

Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>) portal should be directed to Grants.gov help desk. Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern Time Email: support@grants.gov.

Deadline for invited, full proposal submission is 11:59 p.m. Eastern time. Therefore, there are approximately three-hours during which the Grants.gov help desk will NOT be available. Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. *Proposals received after the deadline will not be evaluated.*

Grants.gov will notify Principal Investigators (PIs) of changes made to this Funding Opportunity and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

B. National Technical Information Service

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

C. Commonly Made Mistakes

- Not obtaining or confirming the organization’s [DUNS number](https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) (https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) well before the proposal submission deadline.

- Not obtaining or confirming the organization’s registration with the [Central Contractor Registry \(CCR\)](http://www.ccr.gov/) (<http://www.ccr.gov/>) well before the proposal submission deadline.
- Failing to request “send me change notification emails” from [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>).
- Not contacting [help desks](#) until just before or after deadlines.
- Not completing the Pre-proposal submission before the mandatory deadline.
- Using an incorrect grants.gov application package to submit a proposal through grants.gov. Each funding opportunity requires a specific application package.
- Uploading attachments into incorrect grants.gov forms.
- Attaching files in the wrong location on grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Sub award Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit full proposal by submission deadline.

II. Funding Opportunity Description

A. Program History and Objectives

The Vision Research Program was established in fiscal year 2009 (FY09) to provide support for scientifically meritorious research. Investigators continue to assess new technologies and therapies to address the ocular issues of service members. Current research targets the causes, effects and treatment of eye damage and diseases that, despite their different mechanisms and pathogenesis, all have a common end result: degeneration of the critical components of the eye and impairment or loss of vision. In order to implement therapeutic strategies to prevent or treat visual problems common to combat soldiers, the military wants to develop and validate compounds and strategies.

The US Army Medical Research and Materiel Command (USAMRMC) is soliciting research that targets the various causes, effects and treatment of visual injury resulting from exposures to the elements during combat operations, and damage from explosive devices. The results of this research are intended to be used to ensure and sustain combat readiness. Translational and clinical research efforts are sought to ensure that results of scientific research will be used to directly benefit and preserve the human lives of military and veteran populations. Preliminary research Pre-proposals are required and will provide the basis for invited full proposals. Full proposals will be reviewed by an independent scientific peer review panel and qualified projects will be selected for funding by a programmatic panel.

If the research is not relevant to the currently advertised TATRC goals and critical areas identified, the Government reserves the right to administratively withdraw the full proposal. The

Government also reserves the right to reassign the full proposal's topic area if submitted under an incorrect topic area.

B. Critical Areas

The need for research is urgent across a range of topics germane to vision research. This funding opportunity invites proposals for research in a number of critical areas:

- Treatments for traumatic brain injury-associated visual dysfunction
- Treatments to slow or stop loss of vision in traumatic optic neuropathies;
- Computational models of mechanisms of primary blast injury to the eye and vision system
- Methods to test visual dysfunction in the presence of cognitive impairment
- Treatments for blast and burn injury to ocular structures.

The research projects must be tailored for use within a military milieu across field, garrison, air, shipboard, primary care, or combat settings. Other contextual factors such as, but not limited to, individual, peer, family, community, culture and social, that may affect the selection, implementation, and outcomes of empirically validated research should be addressed.

It is expected that full proposals will articulate a) a thorough review and knowledge of the scientific literature relevant to the nature of the proposed study, b) a theoretically and hypotheses driven approach, and c) potentially rapid translation into clinically and operationally relevant military applications. (Submit supporting data as relevant.)

Encouraged are applications ranging from basic/theoretical to applied research. With a basic approach, applications are encouraged that lend themselves to research that may lay the foundation for new fields of clinical investigation and treatment. Also, the program may support large-scale research projects that accelerate critical breakthroughs, early and applied research employing innovative technologies, and new approaches to improve the synergy and interactions among multi-skilled, interdisciplinary research teams.

C. TATRC Award Description

Anticipated Instrument Type(s)

USAMRMC implements its extramural research program predominantly through the award of assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the recipient and the Government will be a matter of negotiation prior to award. The supporting contracting office, USAMRAA, will negotiate and award proposals selected for funding.

Proposals which include clinical trials are not supported by this award mechanism.

3. Eligibility

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) will use 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. PIs must be independent investigators at any academic level that possess the skills, knowledge, and resources necessary to carry out the proposed research.

Eligible Institutions include nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and commercial firms. Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) are encouraged to submit proposals for review and funding consideration under this announcement.

D. Funding

The amount available for funding for the FY09 VRP is approximately \$5.2M. Additional funding may become available to support this program. The VRP anticipates funding six to ten awards. Award applications may total up to the total available appropriation, inclusive of both direct and indirect costs. Projects requiring lower levels of funding may also be submitted and are encouraged. Reasonableness of budget for the proposed research is a component of the peer review evaluation process. Strong justification must be provided to support the requested budget. (Maximum single award amount not to exceed \$2M; Maximum period of performance not to exceed four (4) years.)

Funding of proposals received in response to this funding opportunity is contingent upon the availability of Federal funds for this program.

Within the guidelines provided in the Application Instructions, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs
- Research-related subject costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions
- Travel to required meetings (i.e. Product Line Review [PLR] & Integrating Integrated Product Team [IIPT])
- Indirect costs
- Other direct costs

E. Award Administration

At the Government's discretion and expense, the PI(s) may be requested to participate in a pre-award meeting.

The transfer of an award to another institution is strongly discouraged. Approval of a transfer request from an institution will be at the discretion of the Grants Officer.

1. Site Visits

During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior funding and should be coordinated through the USAMRAA Contracting/Grants Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DOD personnel, are also encouraged to visit the PI during their award efforts. The visits must all be coordinated with the Contracting/Grants Officer and are intended for technical discussion and monitoring of progress of the funded project.

2. Reports, Presentations and Meetings

Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports due to the government. Reporting requirements may include the following:

- a. Quarterly reports that outline the accomplishments and progress for that period.
- b. Quarterly Standard Form Report, SF 425, Federal Cash Transaction Report, used for grants and cooperative agreements that track the expenditure of funds on the project.
- c. Annual reports that consist of detailed summaries of scientific issues, accomplishments and human research usage during the project.
- d. A final report that details the findings and issues of the completed project.
- e. Copies of all scientific publications and presentations as a result of this funding.
- f. Abstracts suitable for publication in relation to planned meetings.
- g. Presentation by the Principal Investigator (PI) at the Product Line Review (PLR) that details the status of a project to a panel of subject matter experts. Travel and other costs related to PLR attendance should be included in the budget submission.

III. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) Pre-proposal submission and (2) Full proposal submission. *Pre-proposal submission is a required first step.*

Pre-proposal Deadline:	5:00 p.m. Eastern time, July 30, 2009
Invitation to Submit Full Proposal	5:00 p.m. Eastern time, August 22, 2009
Full Proposal Submission Deadline:	11:59 p.m. Eastern time, October 22, 2009
Funding Notification Letter:	February 2010

The deadline for full proposal submission is 11:59 p.m. Eastern time on October 22, 2009.

Therefore, there are approximately three-hours during which the Grants.gov help desk will NOT be available. **Full Proposals should be submitted at least 72 hours before the deadline. This will allow Grants.gov sufficient time to process full proposals, notify PIs of errors, and allow for resubmission of the revised application package prior to the October 22, 2009 deadline. Please plan ahead accordingly. Initial full proposal submissions and any resubmissions received after the final deadline will not be evaluated.**

Awards should be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2010.

IV. SUBMISSION PROCESS AND APPLICATION INSTRUCTIONS

Proposal submission is a two-step process consisting of (1) a Pre-proposal through <https://tatrc.aibs.org>. and (2) an invited, full proposal through [Grants.gov](http://www.grants.gov) (<http://www.grants.gov/>).

PIs and Organizations identified in the full proposal submitted through Grants.gov should be the same as those identified in the Pre-proposal. If there is a change in PI or organization after submission of the Pre-proposal, the PI must contact the submission helpdesk at: <https://tatrc.aibs.org> or call (703) 674-2500, ext. 207.

A. Pre-proposal Submission

All components must be submitted electronically through <https://tatrc.aibs.org> by **5:00 p.m. Eastern time on July 30, 2009**. The Pre-proposal consists of the components discussed below. Refer to the Application Instructions for detailed information.

- 1. Proposal Information:** Enter the Proposal Information as described in <https://tatrc.aibs.org> before continuing the Pre-proposal.
- 2. Proposal Contacts:** Enter contact information for the PI and Contract Representative (CR). The CR is the organization's business official responsible for sponsored program administration (or equivalent). This is the individual, who will be contacted on matters involving this application in Block 5 of the Grants.gov SF424 Form, if invited to submit a full proposal.
- 3. The Pre-proposal narrative (Limit five pages):** The following text content is required: abstract (brief description of the proposed research and how it applies to the topic area(s) of scientific interest stated in the program announcement); plans and methods; research timeline; deliverables; period of performance; estimated cost of

project; brief description of animal and human use; brief CV for PI and key personnel and list of relevant publications. The Pre-proposal must exclude figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

4. **Submission:** Pre-proposals must be submitted at <https://tatrc.aibs.org>.
5. **Responsibilities:** The PI is responsible for completing the submission at <https://tatrc.aibs.org> and reviewing the submission to ensure compliance with the program announcement requirements.
6. **CR/Authorized Organizational Representative (AOR) Responsibility:** The Pre-proposal does not require approval by either the CR or AOR of the organization before submission.
7. **Pre-proposal submission Deadline:** Full proposals will not be invited or accepted if a Pre-proposal is not submitted by **5:00 p.m. Eastern time on July 30, 2009**.
8. Pre-proposals will be screened by the Vision Research Program (VRP) Integration Panel (IP) in order to identify pre-proposals aligned with the VRP priorities. Invitations to submit full proposals to the FY09 VRP will be sent to those applicants whose pre-proposals are selected for further consideration no later than August 22, 2009. DO NOT submit a full proposal to the VRP09 unless you receive a letter of invitation.

B. Full Proposal Components and Submission

Full Proposal Submission Requirements:

Full Proposal submission will not be accepted unless a Pre-proposal was submitted by the deadline and a full proposal is invited. Full proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

Deadline for full proposal submission is **11:59 p.m. Eastern Time on October 22, 2009**.

Therefore, there is an approximately three-hour period during which the Grants.gov help desk will NOT be available. Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. Please plan ahead accordingly.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the U.S. Army Medical Research Acquisition Activity (USAMRAA) Program Announcement.

C. Mandatory Full Proposal Forms

Each submission must include the completed package of forms identified in the Program Announcement on www.grants.gov for the USAMRMC BAA. The Package includes: SF 424 Research & Related (R&R) Application for Federal Assistance; Research & Related Budget; Research & Related Project/Performance Site Location(s); Research & Related Senior/Key Person Profile and Research & Related Other Project Information. The R&R Subaward Budget Attachment(s) Form is optional (to be used as needed). **NOTE: All Attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the full proposal as a .PDF file.**

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

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

- **Applicant Identifier** box should be filled in with the submitting Institution’s Control Number, if applicable. The Institution’s Office of Sponsored Research should be contacted to determine whether the organization has an Institution Control Number. If there is no Institution Control Number, this field should be left blank.
- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions, the “Application” box should be chosen. For changes that must be made after the original submission, the complete application package must be resubmitted, with the “Changed/Corrected Application” box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable.
- **Block 4 – Federal Identifier Box.** Populated by Grants.gov for an original application. If “Changed/Corrected Application” is entered in Block 1, then manually enter the Grants.gov tracking number (i.e., the Grant ID Number assigned to the original application).
- **Block 5 – Applicant Information.** This is the information for the Applicant Organization, not an individual. The “Person to be contacted on matters involving this application” is the CR or Business Official. This is not the Project Director (PD)/Principal Investigator (PI).
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue service. If applying from a foreign institution, enter 44-4444444.
- **Block 7 – Type of Applicant.** This is for the Applicant Organization, not an individual. This is not the PD or PI.
- **Block 8 – Type of Application.** For all submissions, the “New” box must be chosen.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant’s Project.** Enter a brief descriptive title of the project.
- **Block 12 – Areas Affected by Project.** List the largest political entities affected by the project (e.g., state, county, and city). Enter N/A for not applicable.
- **Block 13 – Proposed Project.** The start date should be 9 months to a year from the deadline for proposal submission for this award mechanism.
- **Block 14 – Congressional Districts Of.** If applying from a foreign institution, enter “00-000” for both applicant and project.
- **Block 15 – Project Director/Principal Investigator Contact Information.** Enter information for the individual (PI) responsible for the overall scientific and technical direction of this application.

- **Block 16 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the project.
- **Block 17 – Is Application Subject to Review by State Executive Order 12372 Process?** Choose option “b. NO, program is not covered by E.O.12372.”
- **Block 18 – Complete Certification.** Check “I agree” box to provide the required certifications and assurances.
- **Block 19 – Authorized Organizational Representative (AOR).** The AOR is the individual with the organizational authority to sign for an application. The “signature of AOR” is not an actual signature and is automatically completed upon submission of the electronic application package. *Hard copies of applications will not be accepted.*
- **Block 20 – Pre-application. Ensure the Pre-proposal Log Number is listed in block 20. Attach invitation to submit full proposal and rename the document with the Pre-proposal Log Number. No other information is required.**

2. Research & Related Other Project Information Form

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

- **Blocks 1 - 5:** This section is self-explanatory in addressing the use of human subjects, the use of animals, proprietary information and environmental impact of the research.
- **Block 6 – Project Summary/Abstract (limit one page) (Attachment 2,** located at www.grants.gov; name “Abstract1.pdf”). The abstract is vitally important to both the peer and programmatic review process. The programmatic review includes an evaluation of the abstract as part of the peer review summary statement; therefore, it is paramount that the investigator submits an abstract that fully describes the proposed work. The abstract must contain the title of the proposal and the name of the PI. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters. Abstracts of all funded proposals may be posted; therefore, proprietary or confidential information should not be included in the abstract. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, significance of the proposed work to the program’s goals, specific aims of the study and the study design. An outline is provided below for preparing the structured technical abstract:
 - Background:** Provide a brief statement of 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 concisely the specific aims of the study.
 - Study Design:** Briefly describe the study design.
 - Relevance:** Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on military health outcomes.

A **sample technical abstract** can be found at www.usamraa.army.mil/pages/pdf/2001_BAA_sample_technical_abstract.pdf. Please note limit of one page.

- **Block 7 – Project Narrative (limit 25 pages) (name “Narrative2.pdf”)** – The Project Narrative includes the **Statement of Work** and the **Body of the Full Proposal** – in that order. There is no form for this information. **The attachments must be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.**

The **Statement of Work (SOW)** is the section of a research award that outlines and establishes the PI and an organization’s performance expectations for which USAMRMC may provide funding. Unlike the general objectives which are agreed to in a grant or cooperative agreement, the contract SOW sets rather specific goals and conditions for each year of the contracted project. The PI and contractor are expected to meet the provisions and milestones of the SOW. (The SOW may be incorporated into the award document and, as such, is subject to release under FOIA.)

A series of relatively short statements should be included which comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included which shows the work statements to be accomplished in each year of the award. The SOW **should not exceed two pages** of single-spaced typing.

Below is a suggested SOW format:

Task 1. Brief overview description of this task (timeframe, e.g., months 1-18):

- 1a. Description of subtask 1a (timeframe, e.g., months 1-4).
- 1b. Description of subtask 1b (timeframe, e.g., months 6-12).
- 1c. Description of subtask 1c (timeframe, e.g., months 1-18).

Task 2. Brief overview description of this task (timeframe, e.g., months 4-36):

- 2a. Description of subtask 2a (timeframe, e.g., months 4-12).
- 2b. Description of subtask 2b (timeframe, e.g., months 13-25).
- 2c. Description of subtask 2c (timeframe, e.g., months 25-30).
- 2d. Description of subtask 2d (timeframe, e.g., months 25-36).

The concise timeline should account for the duration by quarter (Q) or year and scheduling relationships of the major tasks identified in the descriptive SOW above.

Body of Proposal - A detailed description of the research to be undertaken should be submitted. This will include background, hypothesis, objectives, approach, methods, and their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. Evaluation of the proposed research will be influenced by the adequacy of this information. Literature references and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:

1. Background. Provide ideas and reasoning behind the proposed study.

- An overview of the subject, issue and/or problem
- Rationale for the proposed research
- Theory under consideration
- Thorough description and evaluation of the work done on the subject matter and argument to support position under review
- Cite relevant literature references

2. Hypothesis. State the hypothesis to be tested and the expected results.

3. Technical Objectives. State concisely the question to be answered by each research objective.

4. Project Milestones. Identify time-lines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule and performance.

5. Military Significance and Impact Statement. State precisely how the proposed study is responsive to the health care needs and quality of life of members of the Armed Forces who are deployed and/or other populations of interest as appropriate for this solicitation. If a military population(s) will be used in the proposed project, describe the population(s), the appropriateness of the population for the proposed research, and the feasibility of using the population. Explain how the proposed research study is aligned with the critical areas addressed in this funding opportunity. Discuss how the anticipated outcome is suitable for operation in a military field or clinical environment. *State explicitly how the proposed study will have an impact on vision research, if successful.* Explain the potential clinical and operational applications, benefits, and risks.

6. Public Purpose. Provide a concise, detailed description of how this research project will benefit the general public.

7. Methods. Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. If recruiting human participants, describe the recruitment process:

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

- Describe the study intervention. Briefly describe the data collection procedures and interaction(s) with the participants, detailing how frequently and for what duration the investigator will interact with the participant (e.g., initial interview, followed by weekly group psychotherapy sessions, each 50 minutes in duration, for 10 weeks).

8. Transition Plan. Provide information on the methods and strategies proposed to move the product to the next phase of development (e.g., larger study, clinical practice, military unit, etc.) after the successful completion of the award. The plan should include details of potential funding sources, collaborations, other resources that will be used to provide this continuity of development, and a potential timeline for field deployment.

- **Block 8 – Bibliography & References Cited (name “References3.pdf”).** List the references in the order they appear in the proposal narrative. Use a reference format, which gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.
- **Block 9 – Facilities & Other Resources (name “Facilities4.pdf”).** Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to 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.
- **Block 10 – Equipment (name “Equipment5.pdf”).** Include a description of existing equipment to be used for the proposed research project. There is no form for this information.
- **Block 11 – Other Attachments.** Include other items appropriate to the proposal.
 - **Multimedia Objects, Photographs, Illustrations, Graphs, etc. (name “graphs6.pdf”).** 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 megabytes (MB). Since some reviewers work from black and white printed copies, applicants 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, graphs etc. must be submitted JPEG format only (no bitmaps or TIFF).
 - **Acronyms and Symbol Definition (name “Acronyms7.pdf”).** Provide a glossary of acronyms and symbols, which might not be familiar to reviewers who are not current in the proposal, and research area.
 - **Collaboration and Joint Sponsorship (name “Collaborations8.pdf”).** Provide letter(s) supporting stated collaborative efforts, which are provided at no cost, and are necessary for the project's success. Describe present or prospective joint sponsorship and assistance agreements of any portion of the program outlined in

the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. If the PI is a practicing clinician, the institutional support letter must clearly demonstrate a commitment to the clinician's research.

- **Certificate of Environmental Compliance (name "COEC9.pdf")**. Information regarding environmental compliance must be provided with the full proposal (**Attachment 3**, located at www.grants.gov).
- **Research Involving Human Participants and/or Anatomical Substances (name "HRPO10.pdf")**. Research Awards funded by the USAMRMC require a second tier review by the Human Research Protection Office (HRPO) for the use of human participants, the use of human data, and the use of human anatomical substances prior to implementation. Therefore, the PI must address all pertinent issues relating to the use of human participants and/or data in the proposed research. Include the required approvals, forms and information as specified on the HRPO website, <https://mrmc.detrick.army.mil/rodorphrpo.asp> Research Involving Human subjects and/or anatomical substances. Full proposals may be submitted without protocols for human use. **However, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments.** The contracting office may grant exceptions in situations where human use is not expected to occur until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.
- **Research Involving Animals**. Research Awards funded by the USAMRMC require a second tier review for the use of animals prior to implementation. Therefore, the PI must address all pertinent issues relating to the use of animals in the proposed research. Include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as specified on the Animal Care and Use Review Office (ACURO) website <https://mrmc.detrick.army.mil/rodorpaurd.asp>. Research conducted under USAMRMC sponsorship that generates preclinical safety data intended to support a research or marketing permit for products regulated by the Food and Drug Administration must be in conformance with the Good Laboratory Practices. Full proposals may be submitted without protocols for animal use; **however, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments.** The contracting office may grant exceptions in situations where animal use is not expected to occur until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.
- **Facility Safety Plan**. The facility safety plan is outlined in (name "Safety11.pdf") (**Attachment 4** located at www.grants.gov) and must be completed and included in the full proposal.
- **Representations & Certifications (name "RepCert12.pdf")**. The form for contracts, located at <http://orca.bpn.gov>. ORCA is an e-Government initiative that was designed by the Integrated Acquisition Environment (IAE) to replace the paper based Representations and Certifications process. The form for

Representations for Assistance Agreements (Grants & Cooperative Agreements) is identified as **Attachment 5**, located at www.grants.gov.

- **Certifications and Assurances for Assistance Agreements (name “Compliance13.pdf”)**. The required Assurances are outlined in **Attachment 6**, located at www.grants.gov. By signing and submitting a proposal or accepting an award, the recipient is concurring with the specified assurances and certifications, in compliance with the DoD 3210.6-R, Department of Defense Grants and Agreements Regulations, Part 22, Appendices A and B.

All attachments must be submitted in PDF format.

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.

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

PI Biographical Sketch: Four-page limit. Named “Biosketch_LastName.pdf” in which “Last Name” is the last name of the PI.

4. Research & Related Budget Form

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

The program does not allow for renewal of or supplementation of existing awards.

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

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

- **Maximum Obligation:** The USAMRMC does not amend awards to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the regulations and principles:
 - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense

FAR Supplement Part 31, Contract Cost Principles and Procedures (<http://farsite.hill.af.mil>).

- **Educational Institutions:** 2 CFR Part 220, Cost Principles for Educational Institutions (<http://www.gpoaccess.gov/cfr/index.html>).
- **Nonprofit Organizations:** 2 CFR Part 230, Cost Principles for Nonprofit Organizations (<http://www.gpoaccess.gov/cfr/index.html>). OMB Circular A-133, Audits of States, Local Governments, and Nonprofit Organizations (<http://www.whitehouse.gov/OMB/circulars/index.html>).
- **State, Local, and Tribal Governments:** 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (<http://www.gpoaccess.gov/cfr/index.html>).
- **Cost of Preparing Proposals:** The cost of preparing proposals in response to this Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant award. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18 and 2 CFR Parts 220 and 230.

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

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

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

An itemized list of proposed permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification (Section K), to include:

- **Vendor Quote:** Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
- **Historical Cost:** Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
- **Estimate:** Include rationale for estimate and reasons for not soliciting current quotes.
- **Special test equipment to be fabricated by the contractor for specific research purposes and its cost.**

- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.
- Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.
- Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

Section D – Travel:

- **Travel costs to attend one scientific/technical meeting.**
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included.
- **Travel to required meetings.** Funds for the PI to attend two Department of Defense military research-related meetings to be determined during the performance period.

Justification for all travel costs should be provided. Travel outside the United States, including between foreign countries, requires prior approval from the grant officer 60 days before travel, unless identified in the proposal that is part of the award.

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

Section F – Other Direct Costs (as applicable):

Section F.1 – Materials and Supplies (Consumables): The justification (to be included in Section K) supporting material and supply (consumable) costs should include a general description of expendable equipment and supplies.

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 – Sub award/Consortium/Contractual Costs: On the project's Research and Related Budget Form, enter the total funds requested for (1) all sub

award/consortium organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

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

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

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

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

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

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

Section H – Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

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

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

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

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

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

5. Research & Related Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Please note that each additional research site requesting funds will require a subcontract budget.

6. R&R Sub Award Budget Attachment(s) Form (if applicable)

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

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

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

A description of services or materials that are to be awarded by subcontract or sub grant 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 sub awards:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or sub grantee, if known, and an explanation of why and how the subcontractor or sub grantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;
- The proposed acquisition price; and
- The applicant’s cost or price analysis for the sub grant or subcontract proposed price.

C. Formatting Guidelines

Invited, full proposals should be submitted no later than October 22, 2009. An award decision should be rendered by the Government no later than 90 days. Forms and information supporting the submission of a full proposal are located at www.grants.gov.

The proposal must be clear and legible. Attachments must conform to the following guidelines:

- **Document Format:** All attachments must be in PDF.
- **Type Font:** 12 point, 10 pitch (Times New Roman)

- **Spacing:** Single-spacing between lines of text
- **Margins:** 1.0 inches on all sides
- **Color, 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 megabytes (MB). Since some reviewers work from black and white printed copies, applicants 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; bitmaps or TIFF formats are not allowed.
- **Acronyms:** Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations and symbols.
- **Language:** English
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the application are encouraged.
- **Headers and Footers:** Should not be used.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB.

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

D. Compliance Guidelines

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

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.

- Spacing is less than specified in the formatting guidelines.
- Budget is missing.
- Scientific Peer and/or Military Relevance Reviewer(s) have not declared a COI but are found to have involvement with the applicant prior to or during the review.
- FY09 VRP member(s) are named in the proposal.
- FY09 VRP member(s) are found to be involved in any capacity in the Pre-proposals and proposal processes including but not limited to concept design, proposal development, budget preparation, and the development of any supporting document.
- FY09 VRP member(s) communicated program priorities prior to the deadline for proposal submission listed in this program announcement.

For any other sections of the Pre-proposals or Full proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for scientific peer review or military relevance review. Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for scientific peer review or military relevance review.

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

V. INFORMATION FOR PRE-PROPOSAL REVIEW

A. Pre-proposal Review: All pre-proposals will be reviewed by the VRPIP.

B. Pre-proposal Screening Criteria:

- **Research Strategy and Objectives:**
 - Feasibility of successful implementation of the proposed experimental design, rationale, methods, and analyses.
- **Impact:**
 - How the proposed research will address one or more of the FY09 VRP focus areas listed under section II-B.
- **Projected Budget:**
 - How the budget is appropriate for the proposed research.

VI. INFORMATION FOR FULL PROPOSAL REVIEW

A. All Invited Full Proposals Review and Selection Overview

All invited, full proposals will be evaluated by scientists and clinicians using a two-tier review process. The first tier includes a scientific peer review of proposals against established criteria for determining scientific merit. The second tier consists of a military relevance review of proposals against established criteria and a programmatic review that compares submissions to

each other and then recommends proposals for funding based on scientific merit, military relevance, and the overall goals of the program.

The scientific peer, military relevance, and programmatic review processes are conducted confidentially 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 corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Likewise persons involved in the proposal review process are prohibited from communicating the program priorities, other than what is listed in this program announcement, to PIs and/or being involved in the proposal development (including the PREPROPOSAL process, concept design, budget, and supporting documentation). Violations of these prohibitions will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality of the scientific peer, military relevance, and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

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

B. REVIEW CRITERIA

1. First Tier Review

Scientific peer review: All proposals will be evaluated according to the following criteria, which are in descending order of importance:

- **Impact**
 - How the results of the proposed study will affect the magnitude and scope of the VRP.
 - How the proposed study addresses one of the funding opportunity topic areas.
- **Study Design**
 - How the scientific rationale and preliminary data, including critical review and analysis of the literature, and clinical evidence support the proposed study and its feasibility.
 - The theoretical or conceptual framework from which the study is premised
 - How the aims, hypotheses, experimental design, methods, data collection procedures, and analyses are developed.
 - How the logistical aspects of the proposed study (e.g., communication plan, data transfer and management, and standardization of procedures) meet the needs of the proposed study.

- How the recruitment, informed consent, and screening processes for volunteers will be conducted to meet the needs of the proposed study.
 - How the inclusion, exclusion, and randomization criteria meet the needs of the proposed study.
 - Evidence the PI will have access to any military populations required for the study, if applicable.
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
 - How the data analysis plan is consistent with the study objectives.
 - How the transition plan describes field or clinical deployment of the product, pharmacologic agent, behavioral intervention, clinical guidance, and/or emerging approach and technology, if applicable.
 - Whether there is evidence that the PI has or can secure additional funding, or whether the PI clearly described potential options to secure the additional funding needed to bring the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology to the next study phase and/or field deployment, if applicable.
 - How the proposed resources will be used to provide continuity of development/deployment and support the likelihood of success, if applicable.
- **Personnel**
 - How the study team’s background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease/condition, and clinical studies).
 - How the levels of effort of the clinical team are appropriate for successful conduct of the proposed study.
- **Environment**
 - How the evidence indicates an appropriate scientific environment, to support the project/study.
 - Evidence for appropriate institutional commitment from each participating institution.
 - How the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed study.
- **Budget**
 - How the budget is appropriate for the proposed research.

2. Second Tier Review

Programmatic review by VRP: All proposals will be evaluated according to the following criteria, which are of equal importance.

- **Responsiveness to funding opportunity topic areas,**
- **Ratings and evaluations of the scientific peer reviewers,**
- **Military relevance,**
- **Programmatic relevance, and**

- **Program portfolio balance.**

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 VRP members and recommended for funding to the Commanding General, USAMRMC.

VII. GRANTS.GOV INFORMATION

A. PUBLIC LAW 106-107

The Federal Financial Assistance Management Improvement Act of 1999, also known as Public Law 106-107 (P.L. 106-107), was enacted on November 1999. The purposes of the Act 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.

B. GRANTS.GOV

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between grant applicants and the Federal agencies that manage grant funds. The grant community, including commercial firms, educational institutions, nonprofit organizations, and state, local and tribal governments 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, USAMRMC requires proposals submitted in response to the BAA to be submitted through Grants.gov APPLY. This requires that Organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual Principal Investigators (PI)/Project Directors (PD) DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register. The registration process can take several weeks so please register as soon as possible.

Organizations that submit a Pre-proposal and are subsequently invited to submit a full proposal under the BAA will be directed to submit through Grants.gov APPLY. Early planning with your organization will facilitate this process. Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov.

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 the Central Contractor Registry (CCR). Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp.

1. Applicant Organization Must Have a Data Universal Number System (DUNS)

Number: An organization will need a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company [Dun & Bradstreet](http://fedgov.dnb.com/webform/displayHomePage.do) (<http://fedgov.dnb.com/webform/displayHomePage.do>). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (<http://fedgov.dnb.com/webform/index.jsp>). Organizations located outside of the United States can request and register for a DUNS number online via [web registration](#).

2. Applicant Organization must be registered with the Central Contractor Registry (CCR): An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates institution information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. *As CCR registrations do expire; PIs should verify the status of their organization's CCR registration well in advance of the proposal submission deadline.*

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

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

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

An AOR must first register with the Grants.gov credential provider at <https://apply.grants.gov/OrcRegister> to obtain a username and password. The AOR must then register with Grants.gov for an account at <https://apply.grants.gov/GrantsgovRegister>. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email

VIII. ADMINISTRATIVE INFORMATION

The USAMRMC executes its extramural research program through the award of contracts and assistance agreements (grants and cooperative agreements). **The type of instrument used to**

reflect the business relationship between the recipient and the Government will be a matter of negotiation prior to award. USAMRMC's supporting Contracting Office, USAMRAA, will process proposals selected for funding.

A. Excluded Parties List

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The 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 DODGAR 25.1125).

B. Administrative Requirements

A recipient organization should meet certain minimum standards pertaining to institutional support, financial resources, and prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circulars at www.whitehouse.gov/omb). Investigators are cautioned that awards are made to organizations, not individuals. The principal investigator (PI) must submit a proposal through an organization and be employed an organization to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017). Should the PI of a funded project leave the recipient institution, both the PI and institution must contact USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify USAMRAA prior to the PI leaving the institution.

By submitting a proposal and accepting an award, the recipient organization is certifying the investigators' credentials were examined and verify the investigators are qualified to conduct the proposed study and use human research participants.

C. J-1 VISA Waiver

Organizations located outside of the U.S. may submit in response to this Program Announcement; however, it is the organizations' responsibility to ensure 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. **In addition, the Government will not provide funds to support scientists from terrorist countries.** Additional information on J-1 VISA Waivers can be located at the following Department of State web site: travel.state.gov/visa/temp.

D. Disclosure of Information outside the Government

Proposals will only be disclosed outside of the Government for the sole purpose of technical evaluation. The USAMRMC obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

E. Government Obligation

Only a warranted Contracting/Grants Officer may obligate the Government to the expenditure of funds for awards under this Program Announcement. The Government does not fund preparation of proposals or support research that is inferred from discussions with technical project officers.

F. Integrity of Review Process

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

Violations of the nondisclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the scientific peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards.

G. Disclosure of Proprietary Information Included in a Proposal

Proprietary information submitted in a proposal may be disclosed outside the Government for the sole purpose of technical evaluation. The US Army Medical Research and Materiel Command (USAMRMC) will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

H. Award Negotiation

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

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

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

I. Title to Inventions and Patents

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

J. Contracted Fundamental Research

Any awards under this PA to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meets the DOD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the contract or grant.

IX. INSTRUCTIONS AND GUIDELINES FOR REGULATORY REQUIREMENTS

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

Concurrent with the US Army Medical Research Acquisition Activity (USAMRAA) negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form to be submitted upon request.

A. Certificate of Environmental Compliance

The [Certificate of Environmental Compliance](#) will be requested prior to award negotiations. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

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.

B. Research Involving Human Subjects or Human Data

Research Involving Human Subjects: *Use of Human Subjects and Human Biological Substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO) in addition to local Institutional Review Boards (IRBs). 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 IRB.*

The PI must address pertinent issues relating to the use of human participants in the proposed research. Include the required approvals, forms and information as specified on the Human Research Protection Office (HRPO) website: <https://mrmc.detrick.army.mil/rodorphrpo.asp>

During the regulatory review process for research involving human subjects, the recommendations of the second tier Human Research Protection Office (HRPO) must be addressed and approved by the local Institutional Review Board (IRB). It is strongly recommended that investigators carefully read the “Guidelines for Investigators” found at <https://mrmc.amedd.army.mil/docs/rcq/GuidelinesforInvestigators.pdf> (specifically, pages 28-47 for protocol and consent guidance). The time to approval depends greatly on adherence to these guidelines in a clear and comprehensive manner. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission. TATRC regulatory personnel can provide a pre-review to assist with meeting HRPO requirements prior to submission to the IRB.

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

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

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

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

The following **must appear in the consent form:**

- A statement that the DOD or a DOD organization is funding the study
- A statement that representatives of the U. S. Army Medical Research and Materiel Command (or the DOD) are authorized to review research records.
- In the event that a separate HIPAA authorization is required, representatives of the USAMRMC should be listed as one of the parties to whom private health information may be disclosed.
- For Greater than minimal risk research, the following paragraph should be included in the consent form after the institutional provisions for medical care for research related injury are described:

"If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the

hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, (name and telephone number of principal investigator). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) office of the staff judge advocate (legal office) at 301- 619 - 7663/2221."

Note: This language may not be necessary for intramural protocols, protocols conducted within a military medical treatment facility, VA protocols, and protocols in which the institution or sponsor is providing free medical care.

3. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; <http://www.dtic.mil/biosys/downloads/title10.pdf>) applicable to DOD-sponsored research before writing a research protocol. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Furthermore, and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. PIs should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

Note: This statute is only applicable to certain intervention studies. 10 USC 980 does not apply to retrospective studies, observational studies, blood draws and tissue collections. Contact HRPO for further clarifications regarding applicability of 10 USC 980 to your specific protocol.

4. Medical Monitor Requirement. An independent medical monitor must be identified in the protocol for all greater than minimal risk protocols. A CV or biosketch and human subjects protection training is provided. The medical monitor must have no apparent conflict of interest. The medical monitor should not be under the supervision of the principal investigator or other investigators or research staff. It is acceptable to provide appropriate compensation to the medical monitor for his or her services.

The role of the medical monitor is described in the protocol and is consistent with DOD guidance. Medical monitors should be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual volunteer management and safety. Medical monitors must be independent of the investigative team and possess sufficient educational and professional experience to serve as

the volunteer advocate. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of research project: volunteer recruitment, volunteer enrollment, data collection, or data storage and analysis. The medical monitor provides an independent evaluation of serious adverse events and unanticipated problems involving risk to subjects or others to the IRB and the HRPO. The medical monitor may be assigned to discuss research progress with the principal investigator, interview volunteers, consult on individual cases, or evaluate adverse event reports. Medical monitors shall promptly report discrepancies or problems to the IRB and the HRPO. They shall have the authority to stop a research study in progress, remove individual volunteers from a study, and take whatever steps are necessary to protect the safety and well-being of research volunteers until the IRB can assess the medical monitors report

5. Recruitment of Military Personnel. Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements.

A letter of support from the Commander of military facilities or units in which recruitment will occur or the study will be conducted will be requested. Some sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command should not be involved in the recruitment of military personnel and should not encourage or order service members to participate in a research study. Per DOD Directive 3216.2, an ombudsman should be employed when conducting group briefings with Active Duty personnel to ensure that volunteers understand that participation is voluntary and may be recommended in other situations as well, especially when young enlisted service members are recruited who are trained to follow orders. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

6. Payment to Military Personnel. Under 24 USC 30, payment to Active Duty military personnel for participation in research is limited to blood donation and may not exceed \$50 per blood draw. Active Duty research volunteers may not receive any other payment for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

7. Confidentiality for Military Personnel. Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties or discharge. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the Military Code of Justice including incarceration and dishonorable discharge. For aviators, losing flight status due to a physical or psychological concern is an issue.

8. Research Involving the Use of Animals: Research involving animals will be considered. Specific documents relating to the use of animals in the proposed research will be requested if the proposal is selected for funding (these documents should not be submitted with the application. The Animal Care and Use Review Officer (ACURO), a component of the USAMRMC Office of Research Protections (ORP), must review and approve all animal use

prior to the start of working with animals. PIs must complete and submit the animal use appendix titled “ACURO Animal Use Appendix for Research Involving Animals,” which can be found on the ACURO website <https://mrmc.amedd.army.mil/AnimalAppendix.asp>. Allow 2 to 4 months for regulatory review and the approval processes for animal studies.

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

X. INSTRUCTIONS FOR REPORTS

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

A. Research Progress Reports

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

B. Fiscal Reports

Quarterly fiscal report requirements may include the Standard Form Report, SF 425, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

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.