General Application Instructions

Medical Practice Initiative

W81XWH-12-JPC1-MPI-PSD

Table of Contents

I. Helpful Information **2**
A. Receiving Emails from the TATRC and Grants.gov 2
B. Agency Contacts 2
II. Submission Information **3**
A. Submission Dates and Times 3
B. Content and Form of Pre-application Submission. 3
C. Content and Form of Full Application Submission 5
Appendix 1. Eligibility Information **18**
Appendix 2. Formatting Guidelines **19**
Appendix 3. Grants.gov Requirements **20**
Appendix 4. Administrative Information **22**
Appendix 5. Regulatory Requirements **24**
Appendix 6. Acronym List **29**

I. HELPFUL INFORMATION

A. Receiving emails from the TATRC and **Grants.gov.**

To ensure that all email correspondence is delivered correctly and is not treated as spam by email programs, place the following domains into the safelist/whitelist: army.mil, amedd.army.mil, us.army.mil, tatrc.aibs.org, tatrc.org, and grants.gov.

B. Agency Contacts

1. **Help Desk:** Questions related to the submission of the Pre-application should be directed to the Pre-application help desk.

   Phone: 1-703-674-2500, ext. 207

   Email: tatrc@aibs.org

2. **Grants.gov Contact Center:** Questions related to Full Application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). **Note that the TATRC Pre-application Help Desk is unable to provide technical assistance with Grants.gov submission.**

   Phone: 1-800-518-4726

   Email: support@grants.gov

3. Questions related to the Program Announcement/Funding Opportunity content or submission requirements should be directed via email to programannouncements@tatrc.org . **You must include the Funding Opportunity number W81XWH-12-JPC1-MPI-PSD in the subject line of the email.**

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) Pre-application (pre-proposal) submission through the MPI-PSD Pre-application submission portal at https://jpc1-mpi-psd.aibs.org and (2) Full Application (Full Proposal) submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative Applications.

The Principal Investigators (PIs) and organizations identified in the Full Application submitted through Grants.gov should be the same as those identified in the Pre-application. ***For specific instructions regarding changes to the PI or organization, refer to the Program Announcement/Funding Opportunity.***

On occasion, the Government may update or change the original version of the Full Application package in Grants.gov. The applicant must use the new version of the Full Application package; Full Applications submitted with the original version of the Full Application package may not be accepted by Grants.gov. ***Sign up in Grants.gov (http://www.grants.gov/) for "Send me change notification emails"*** by following the link on the Synopsis page for the specific Program Announcement/Funding Opportunity.

A. Submission Dates and Times

All Pre-application and Full Application components must be submitted by the deadlines identified on the title page of the Program Announcement/Funding Opportunity. Material submitted after the deadlines, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet any one of the deadlines shall result in Application rejection.

Both the TATRC Pre-application submission portal and Grants.gov have a number of required steps that must be completed before submissions will be accepted. Make sure to allow adequate time for completion of all Pre-application and Full Application steps by their respective deadlines.

B. Content and Form of Pre-Application Submission

All Pre-application components must be submitted through the MPI-PSD Program Announcement submission portal at https://jpc1-mpi-psd.aibs.org by the deadline specified on the title page of the Program Announcement/ Funding Opportunity; otherwise, the Pre-application will not be accepted.

- **Application Information:** Enter the Information as described at https://jpc1-mpi-psd.aibs.org before continuing the Pre-application. See Program Announcement or submission website for more detailed information.
- **Responsibilities:** The PI is responsible for completing the submission at https://jpc1-mpi-psd.aibs.org and reviewing the submission to ensure compliance with the Program Announcement requirements.

- **Authorized Organizational Representative (AOR) Responsibility:** The Pre-application does not require approval by the AOR of the organization before submission.
- **Pre-application Submission Deadline:** Full Applications will not be invited or accepted if a Pre-application is not submitted by the deadline provided on the title page.

Pre-Application (Pre-proposal) Screening - Pre-proposal applications to this PA must provide a working hypothesis, background information supporting the research efforts, relevant methodologies to support the anticipated research, military relevance, preliminary budget (including PI, Co-PI and relevant team members, budget summary of project areas, as well as any equipment purchases for over $10,000.00), brief CV of the PI, references, and a conclusion/summary.

Qualifying pre-proposals may be selected for a full proposal invitation. No feedback will be provided regarding reasons for non-invitation of full proposal submissions.
Pre-proposals will be screened based on the following criteria:

- **Scientific Merit**
  - Quality of hypothesis(es) & research methods
  - Strength of study design
  - Size of the physician population to be studied? Is it adequate?
  - Demonstrated ability to obtain necessary EHR based and physician research data
  - Quality of predictive model
  - Does the proposal include a high level of innovation?
  - Does the proposal offer novel and creative approaches that will provide information that would be useful to construct an automated training system in the future based upon frequency of exposure as determined by EHR analysis?

- **Organization(s) & Personnel**
  - Appropriateness of expertise and knowledge in the relevant disciplines.
  - Team balance, if applicable
  - Appropriateness of intellectual property plan, if applicable, for the proposed research and development effort.

- **Military Relevance**
  - How will the research advance JPC1 MPI goals and future plans?
  - Is the data transferable to a military practioner population? (The use of military subjects for research is not required.)

- **Notification of Pre-proposal Screening Results**

Following the pre-proposal screening, the PI will be notified of whether or not they are invited to submit a full proposal; however, pre-proposal review feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal will not be provided. DO NOT submit a Full Application unless you receive a letter of invitation.

Pre-proposal notification dates (approximate date) are indicated on the title page of this Program Announcement / Funding Opportunity.

C. Content and Form of Full Application Submission

Each Full Application submission must include the completed Grants.gov Application package of forms associated with the specific Program Announcement/Funding Opportunity in Grants.gov (http://www.grants.gov/). Refer to Appendix 3 for additional information on Grants.gov requirements.

It is strongly recommended that Full Applications be submitted at least 72 hours before the Full Application submission deadline to allow time for Grants.gov validation of the Application and, if necessary, resubmission as a "Changed/Corrected Application" prior to the deadline.

A compatible version of Adobe Reader must be used to view, complete, and submit the Grants.gov Application package. ***Grants.gov will reject an Application package that is opened at any point in time with an incompatible version of Adobe Reader.*** If multiple individuals are working on the same Application package, all must use a compatible version of Adobe Reader. If an Application is rejected due to use of an inappropriate Adobe Reader version, a new Application package must be downloaded, completed, and submitted using a supported version of Adobe Reader.

Visit the following website to verify that the version of Adobe Reader being used is compatible with Grants.gov: http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp, or download a no-cost compatible version at http://www.grants.gov/help/download_software.jsp.

Proposal Log Number

During the Pre-application process, each submission will be assigned a unique and separate log number. The corresponding Grants.gov Application package must be submitted using this unique proposal log number. Enter the proposal log number in one of two ways:

- **Manual entry:** Fill in the **Application Filing Name** on the first screen of the Grant Application Package (Figure 1) using only the **proposal log number** assigned during the Pre-application process.
- **System-to-system entry:** If a system-to-system interface with Grants.gov is being used, then enter the proposal log number acquired during the Pre-application process into the **Submission Title** field. ***The Government cannot make allowances/exceptions to its policies for submission problems encountered through using system-to-system interfaces with Grants.gov.***

The Full Application consists of the following components:

Each attachment to the Grants.gov Application forms must be an individual PDF file in accordance with the formatting guidelines listed in Appendix 2.

1. **SF 424 (R&R), Application for Federal Assistance Form –**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:

   - **Block 1 – Type of Submission.** For original 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 with the "Changed/Corrected Application" box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.
   - **Block 2** – Date Submitted. Enter the date the Application is submitted.
   - **Applicant Identifier:** Enter the submitting Institution's Control Number, if applicable. This information can be obtained from the Institution's Office of Sponsored Research. If there is no Institution Control Number, this field should be left blank.
   - **Block 3 – Date Received by State** is not applicable
   - **Block 4a – Federal Identifier Box** will be populated by Grants.gov for an original Application. The Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original Application) must be manually entered for Changed/Corrected Applications.
   - **Block 4b – Agency Routing Identifier**. Not aplicable.
   - **Block 5 – Applicant Information**. Enter the information for the applicant organization. The "Person to be contacted on matters involving this Application" is the AOR.
   - **Block 6 – Employer Identification**. Enter the Employer Identification Number (EIN) or Tax Identification Number (TIN) as assigned by the Internal Revenue Service. If applying from an organization outside the U.S., enter 44-4444444.
   - **Block 7 – Type of Applicant.** Enter the information for the applicant organization.
   - **Block 8 – Type of Application.** Select "New" for all submissions.
   - **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 – Proposed Project.** The actual start date will be determined during negotiations if the Application is recommended for funding.
   - **Block 13 – Congressional District Of Applicant**. If the applicant organization is outside the U.S., enter 00000.
   - **Block 14 – Project Director/Principal Investigator Contact Information.** Enter information for the individual PI responsible for the overall scientific and technical direction of this Application. If outside the U.S., select the appropriate country from the dropdown menu.

- **Block 15 – Estimated Project Funding.** Enter the total funds (direct + indirect/facilities and administrative costs) requested for the entire performance period of the project.
- **Block 16 – Is Application Subject to Review by State Executive Order 12372 Process?** Select option "b. NO, program is not covered by E.O.12372."
- **Block 17 – Complete Certification.** Select the "I agree" box to provide the required certifications and assurances.
- **Block 18 – SFLLL or other Explanatory Documentation.** If applicable, complete and attach Standard Form LLL to disclose lobbying activities pursuant to 31 U.S.C. 1352.
- **Block 19 – Authorized Representative.** Enter the contact information for the applicant organization's authorized representative. The "Signature of Authorized Representative" is not an actual signature and is automatically completed upon submission of the electronic Application package.
- **Block 20 – Pre-application** box and attachment should be used to attach the Pre-application file associated with this proposal. **Pre-application file name should be the eight digit log number assigned to the Pre-application so the number will automatically populate to the Pre-application box.**

2. Research & Related Budget

An estimate of the total proposed research project cost, with a breakdown of all cost categories for each year, must accompany each Application. Provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. ***Include a detailed budget and budget justification.*** The budget justification for the entire period of performance must be uploaded to the Research & Related Budget form after completion of the budget for Period 1. At the time of Application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all costs are current, accurate, and complete. Use the Research & Related Budget form that is available for download on the Grant Application Package page for the Program Announcement/Funding Opportunity in Grants.gov.

Budget Regulations: The following must be adhered to regarding budget calculations:

- **Maximum Obligation:** The US Army Medical Research and Materiel Command (USAMRMC) does not modify awards to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the regulations and principles:
  - **Commercial Organizations:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 231, Contract Cost Principles and Procedures (http://farsite.hill.af.mil).
  - **Educational Institutions:** 2 Code of Federal Regulations (CFR) Part 220 Cost

Principles for Educational Institutions

(http://www.gpoaccess.gov/cfr/index.html).

- **Nonprofit Organizations:** 2 CFR Part 230, Cost Principles for Nonprofit Organizations (http://www.gpoaccess.gov/cfr/index.html). Office of Management and Budget (OMB) Circular A-133, Audits of States, Local Governments, and Nonprofit Organizations (http://www.whitehouse.gov/OMB/circulars).

- **State, Local, and Tribal Governments:** 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (http://www.gpoaccess.gov/cfr/index.html).

- **Cost of Preparing Applications:** The cost of preparing Applications in response to this Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. However, the cost of preparing Applications is an allowable expense to the indirect/facilities and administrative cost as specified in FAR 3 1.205-18, and 2 CFR Parts 220, 225, and 230.
- **Currency:** All costs must be entered in US dollars. Recipients performing research outside of the US should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.

Submit a detailed budget and justification that covers the entire period of performance (not just the first year). The Government reserves the right to request a revised budget and budget justification and/or additional information.

Budget Instructions: Complete the Research & Related Budget form following the instructions below. Begin by entering the organizational Data Universal Number System (DUNS) number, Budget Type, Name of Organization, and anticipated start and end dates.

Section A: Senior/Key Person

- **Prefix; First, Middle and Last Name; and Suffix:** Beginning with the PI, list all senior/key persons from the applicant organization who will be involved in the proposed research project, whether or not salaries are requested. Include all investigators, research associates, etc. If applicable, all investigators outside the applicant organization should be included on the R & R Subaward Budget Attachment(s) Form. Consultant costs should be listed under section F.3.
- **Project Role:** Identify the role of each senior/key person listed. Describe his/her specific functions in the budget justification.
- **Base Salary:** Enter the current annual organizational base salary (based on a full- time appointment) for each individual listed for the proposed research project. Establish labor costs using current labor rates or salaries. Identify and explain in the budget justification any proposed adjustments to salary/wages.
- **Calendar, Academic, and Summer Months:** For each senior/key person including unpaid personnel, list the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.

- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines. Costs for all sponsors must be treated consistently by the applicant organization. Provide documentation to support the fringe benefits (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document) with the budget justification.
- **Funds Requested:** Enter the total funds requested for each senior/key person listed for the proposed research project.

Section B: Other Personnel:

- **Number of Personnel:** For each project role category indicate the number of personnel for the proposed research project, including unpaid personnel.
- **Project Role:** Identify each project role category. Within the budget justification, describe the specific functions of the personnel in each project role.
- **Calendar, Academic, and Summer Months:** For each project role category, list the number of months to be devoted to the proposed research project in the appropriate box.
- **Requested Salary:** Enter the amount of salary requested for this budget period.
- **Fringe Benefits:** Enter the fringe benefits requested for each project role category in accordance with organizational guidelines. Costs for all sponsors must be treated consistently by the applicant organization. Provide documentation to support the fringe benefits (e.g., the current DHHS Rate Agreement or other policy document).
- **Funds Requested:** Enter the total funds requested for each project role category listed for the proposed research project.

Section C: Equipment Description: Major equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit (unless the applicant organization has established a lower limit). Recipients are encouraged to provide all major equipment necessary to conduct the proposed research project. If major equipment is requested, provide a detailed list showing the cost of each item. The budget justification for all major equipment must include:

- **Historical Cost:** Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
- **Vendor Quote:** Provide a copy of the successful vendor's quote. Any equipment purchase should be made in accordance with the recipient's approved purchasing system.
- **Estimate:** Include rationale for estimate and reasons for not soliciting current quotes.
- Special test equipment to be fabricated for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.

- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the recipient with recipient funds, would be capitalized for Federal income tax purposes.

Section D: Travel: Travel costs may include:

- Attending at least one scientific/technical meeting per year. Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity. Include the meeting name, purpose, location and date, if known, in the budget justification.
- Travel associated with the execution of the proposed work (if applicable). Reasonable costs for travel between collaborating organizations should be included and are not subject to the yearly cost limitation on travel to scientific/technical meetings.
- Attending TATRC-required meetings. Costs should not exceed the amount specified in the Program Announcement/Funding Opportunity. Include the meeting name if identified in the Program Announcement/Funding Opportunity and a statement in the budget justification confirming that the PI will attend the required TATRC required meeting.

Section E: Participant/Trainee Support Costs: Enter the funds requested for tuition/fees; health insurance; stipends; travel; subsistence; and other costs.

Section F: Other Direct Costs

- **Materials and Supplies:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies for each year. For materials and supplies costing $5,000 and over per year, provide descriptions, quantities, and unit prices. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal and total costs, proposed vendor, and a copy of the animal per diem cost/rate agreement. If human cell lines are to be purchased, state the source, cost, and description.
- **Publication Costs:** Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
- **Consultant Services:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
- **ADP/Computer Services:** Include the cost of computer services, including computer-based retrieval of scientific, technical, and education information. Include in the budget justification computer service rates at the proposing organization.
- **Subaward/Consortium/Contractual Costs:** Include the total funds requested for (1) all subaward/consortium organization(s) proposed for the research project and (2) any

other contractual costs proposed for the research project. This amount should be supported in the subaward/consortium/contractual costs provided in the R & R Subaward Budget Attachment(s) Form.

All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

- **Equipment or Facility Rental/User Fees:** List proposed equipment or facility rental/user fees. Include appropriate information (hours and rates) in the budget justification.
- **Alterations and Renovations:** Alteration and renovation (A&R) costs can be requested if the costs are essential to accomplish the objectives of the research project and are a minor portion of the overall budget. A description of the existing facility and detailed description of the requested changes, along with a cost estimate, must be included in the budget justification. Costs for the construction of facilities are not allowable.
- **Other Expenses:** Itemize other anticipated direct costs such as communication costs and organizationally provided services. These items should be described in detail and clearly justified. Unusual or expensive items should be fully explained and justified in the budget justification. Organizationally provided services should be supported by the organization's current cost/rate schedule.

  Computers and software are considered to be general office supplies and are not normally allowable direct cost charges unless the computer/software is essential and unique to the proposed research project. If a computer/software purchase is requested, include the following in the budget justification:

  - Detailed description regarding why the computer/software purchase is required to complete the proposed research project.
  - Statement verifying that the requested computer/software is not currently available for use by the PI.
  - Verification that the requested computer/software will be purchased in accordance with applicable cost principles.

  Include itemized research-related subject costs for the proposed research project. These costs are strictly limited to expenses specifically associated with the proposed research project.

Section G: Direct Costs: Include the total direct costs (A-F).

Section H: Indirect Costs: The indirect costs category may include Facilities and Administrative (F&A) costs, overhead, General and Administrative (G&A), and other. The most recent Federal agency approved rate(s) should be applied. If the rate(s) has been approved by other than a Federal agency, indicate the source of the approval.

- Provide details of the direct cost base (modified total direct costs, salary and wage, or other). Identify any costs that have been excluded from the base (in accordance with the approved rate agreement). Also indicate if the rate(s) is an on- or off-site rate(s). If more than one rate is applicable, provide a breakdown of the calculation.
- Provide documentation to support the indirect cost rate (e.g., the current Department of Health and Human Services [DHHS] Rate Agreement or other policy document).

- If a negotiated approved rate(s) does not exist, provide sufficient detail for a proposed rate (adhering to the applicable cost principles) in the budget justification. Organizations can also visit the Department of Health and Human Services (http://rates.psc.gov/fms/dca/negotiations.html), the Office of Naval Research (http://www.onr.navy.mil/Contracts-Grants/manage-grant/indirect-cost-proposal.aspx), and the Defense Contract Audit Agency (http://www.dcaa.mil/) for additional information on indirect rates

Section I: Total Direct and Indirect Costs: Include total costs for the proposed research project.

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

Section K: Budget Justification: Provide a clear budget justification for each item in the budget over the entire period of performance and attach as a single PDF file to section K of the Research & Related Budget form.

Organizations must provide sufficient detail and justification so the Government can determine that the proposed costs are allowable, allocable, and reasonable for the proposed research effort.

Federal Agency Financial Plan (if applicable): Applications from Federal agencies must provide a plan at the end of the budget justification delineating how all funds will be obligated by 30 September 2012, 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 organizations, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to provide funds to a U.S. Government entity except under very limited circumstances provided for in USAMRMC policy, such as:

1) The Recipient can show that such funds will not originate from the USAMRMC award, or
2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or
3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy. Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by the US Army Medical Research Acquisition Activity Contracting/Grants Officer. Examples of exceptional circumstances that could merit approval would be (a) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (b) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used

by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the award.

3. 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. Add additional sites as necessary using the "Next Site" button.

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

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

- **PI Biographical Sketch:** This file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the PI.

- **PI Current/Pending Support:** This file must be titled "Support_LastName.pdf," where "LastName" is the last name of the PI.

  For all existing and pending research support, include the: 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, and list of the specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects.

  If there is no existing or pending support, enter "None." An updated existing and pending support document will be required during award negotiations.

- **Key Personnel Biographical Sketches:** Each file must be titled "Biosketch_LastName.pdf," where "LastName" is the last name of the appropriate individual.

- **Key Personnel Current/Pending Support:** Each file must be titled "Support_LastName.pdf," where "LastName" is the last name for the individual. Refer to content requirements under "PI Current/Pending Support" listed above.

5. Research & Related Other Project Information: This form is self-explanatory. 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 (**form provided under the Program Announcement at www.grants.gov**):** 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.

  a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work.

  b. **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  c. **Specific Aims:** State concisely the specific aims of the study.

  d. **Study Design:** Briefly describe the study design.

  e. **Relevance:** Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.

- **Block 7 – Project Narrative** (limit 21 pages) – The Project Narrative includes the statement of work and the body of the proposal – in that order. There is no form for this information. The attachments should 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 one page** of single-spaced typing.

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. This information **should not exceed 20 pages**. 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:

- **Background**. Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- **Hypothesis**. State the hypothesis to be tested and the expected results.
- **Technical Objectives.** State concisely the question to be answered by each research objective.
- **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.
- **Military Significance.** State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.
- **Public Purpose**. If appropriate, provide a concise, detailed description of how this research project will benefit the general public.
- **Methods.** Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For synthetic chemistry proposals include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.

- **Block 8 – Bibliography & References Cited**. 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.** 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. The attachments should be in PDF, in accordance with the formatting guidelines outlined for full proposal preparation.
- **Block 10 – Equipment:** Include a description of existing equipment to be used for the proposed research project. There is no form for this information. The attachments should be in PDF, in accordance with the formatting guidelines outlined for full proposal preparation.
- **Block 11 – Other Attachments.** Include in this section all items listed below as well as

any other documentation not specified elsewhere, that supports the research proposed and could influence the evaluation and selection process.

- **Representations and Certifications for Assistance Agreements**. Representations for Assistance Agreements (Grants & Cooperative Agreements) (located at www.grants.gov)**.**
- **Certifications and Assurances for Assistance Agreements**. 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. (located at www.grants.gov**).**
- **Multimedia Objects, Photographs, Illustrations, Graphs, etc. -** 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 in Microsoft Office or JPEG format only (no bitmaps or TIFF). **If photographs of identifiable patients are provided, release forms must also be submitted with the photographs.**
- **Acronyms and Symbol Definition -** 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 -** 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 of any portion of the program outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal is submitted, information should be sent later as an addendum to the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship.

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

Complete a separate detailed Research & Related Budget form including a budget justification for each subaward (subgrant or subcontract) in accordance with the instructions listed above. Title each individual subaward Research & Related Budget form with the name of the subawardee organization and attach to the R & R Subaward Budget Attachment(s) Form.

All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

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

- Identification of the type of subaward to be used (e.g., cost reimbursement, fixed price).

- Identification of the proposed subcontractor or subrecipient, if known, and an explanation of why and how the subcontractor or subrecipient was selected or will be selected.

- Whether the subaward will be competitive; if noncompetitive, rationale to justify the absence of competition.

- The applicant's cost or price analysis for the subaward that supports the allowability, allocability, and reasonableness of the proposed cost or price.

APPENDIX 1

ELIGIBILITY INFORMATION

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The US Army Medical Research and Materiel Command (USAMRMC) uses the Federal Awardee Performance and Integrity Information System (FAPIIS) to identify recipients ineligible to receive Federal awards. More information about the FAPIIS is available at http://www.cpars.csd.disa.mil/FAPIISmain.htm. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] Part 1125.)

A. Eligible Investigators: Includes all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization. Investigators must meet the specific Program Announcement/Funding Opportunity requirements.

B. Eligible Organizations: Eligible organizations include for-profit, nonprofit, public, and private organizations, such as universities and colleges (including historically black colleges and universities, and minority institutions), hospitals, laboratories, and companies.

C. Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded intramural programs. Federal agencies are required to explain how their applications do not overlap with their intramural programs.

APPENDIX 2

FORMATTING GUIDELINES

All Pre-application and Application documents should be clear and legible, and must conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman.
- **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:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and Pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the Application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the Application are encouraged.
- **Language:** English.
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB.

APPENDIX 3

GRANTS.GOV REQUIREMENTS

The United States Army Medical Research and Materiel Command requires that Applications responding to a Program Announcement/Funding Opportunity be submitted through the Federal Government's single entry portal Grants.gov. In addition to Application submission through Grants.gov, a Pre-application submission to the MPI-PSD Pre-application submission portal (https://jpc1-mpi-psd.aibs.org).

Organizations must register in Grants.gov in order to submit Applications through the Grants.gov portal. The registration process may take several weeks, so organizations should register as soon as possible.

If business is conducted with the Federal Government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a Data Universal Number System (DUNS) number or registration in the Central Contractor Registry (CCR). Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp. Enter the contact information for the applicant.

The following actions are required as part of the registration process:

A. Applicant Organization Must Have a DUNS Number: A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet. If an organization does not have a DUNS number, an authorized business official of the organization can request one by calling 866-705-5711 or by registering online (http://fedgov.dnb.com/webform/displayHomePage.do). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

B. **Applicant Organization Must Be Registered With the CCR:** An organization must be registered with the CCR (http://www.ccr.gov) before submitting a grant Application through Grants.gov or receiving an award from the Federal Government. The CCR validates organization information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. An organization must identify an E-Business point of contact (E-Biz POC) during the CCR registration process.

As CCR registrations have an expiration date, authorized business officials should verify the status of their organization's CCR registration well in advance of the Application submission deadline.

Non-US organizations must obtain a Commercial and Government Entity (CAGE) code prior to registering with the CCR. A CAGE code can be obtained by calling 1-269-961-7766 or online at http://www.dlis.dla.mil/Forms/Form_AC135.asp.

C. Authorized Organization Representative Must Be Registered With Grants.gov:
Individual PIs do not register with Grants.gov; the AOR is required to register. An organization's E-Biz POC must authorize an AOR. An individual may serve as both the E-Biz POC and the AOR. Before submitting an Application, an organization representative must register to submit on behalf of the organization at Grants.gov.

An AOR must first register with the Grants.gov credential provider at http://apply07.grants.gov/apply/OrcRegister to obtain a username and password. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Biz POC for assignment of user privileges. When an E-Biz POC approves an AOR, Grants.gov will send the AOR a confirmation email.

At the time of Application submission to Grants.gov, the AOR is certifying to the best of his/her knowledge that all information provided in the Application is current, accurate, and complete.

APPENDIX 4

ADMINISTRATIVE INFORMATION

A. Disclosure of Proprietary Information Included in an Application

Proprietary information submitted in an Application may be disclosed outside the Government for the sole purpose of technical evaluation. The United States Army Medical Research and Materiel Command (USAMRMC) will obtain a written agreement from the evaluator that proprietary information in the Application will only be used for evaluation purposes and will not be further disclosed or used. All Applications may be subject to public release under the Freedom of Information Act.

B. Award Negotiation

Extramural research programs are implemented predominantly through the award of assistance agreements that are made to an organization, not to the individual Principal Investigator(s) (PI[s]). A representative from the US Army Medical Research Acquisition Activity (USAMRAA) will contact the business official authorized to negotiate at the PI's organization. The award start date will be determined during the negotiation process.

Only an appointed USAMRAA Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. Any preaward costs associated with a research effort are made at an organization's own risk. The incurring of preaward costs by an organization does not impose any obligation on the Government in the absence of appropriations, if an award is not made, or if an award is made for a lesser amount than an organization expected.

C. Administrative and National Policy

The award provisions of Appendix B to Part 22 of the DODGAR 3210.6-R apply to all assistance agreements (http://www.dtic.mil/whs/directives/corres/pdf/321006r22apbp.pdf). Refer to this Applications Instructions, Appendix 5, for further regulatory requirements.

D. Reporting, Presentations and Meetings

The Government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. 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:

- Quarterly reports that outline the accomplishments and progress for that period.
- Quarterly Standard Form Report, SF272, Federal Cash Transaction Report, used for grants and cooperative agreements that track the expenditure of funds on the project.
- Annual reports that consist of detailed summaries of scientific issues, accomplishments and human research usage during the project.

- A final report that details the findings and issues of the completed project.
- Copies of all scientific publications and presentations as a result of this funding.
- Abstracts suitable for publication in relation to planned meetings.
- Presentation at the In Process Review (IPR) that details the status of a project to a panel of subject matter experts. **Travel and other costs related to IPR attendance should be included in the budget submission. Generally, the IPRs will we held at Fort Detrick, Maryland.**

Failure to submit required reports by the established due date may result in a delay or termination of award funding.

E. Organization or Principal Investigator Changes After Awards

Unless restricted by the Program Announcement/Funding Opportunity, a change in organizational affiliation will require the new organization to resubmit the entire Application packet on behalf of the PI. The PI's original organization must agree to relinquish the award. Resubmission will include regulatory documentation to be approved for the new organization. Unless otherwise restricted, changes in PI will be made at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

F. Equipment

Unless otherwise specified in the award, the 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 organization for the Government. However, if the award is subsequently transferred to a new organization, the Department of Defense (DOD) reserves the right to require the transfer of equipment purchased with the award funds to the Federal government or to an eligible third party.

G. J-1 Visa Waiver

Each organization is responsible for ensuring 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.

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 Federally funded research may be held by the recipient 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.

APPENDIX 5

REGULATORY REQUIREMENTS

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

Studies involving animals and studies that meet the definition of non-exempt human subjects research (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances), must be approved through a regulatory review process by the PI's local Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) and by the USAMRMC Office of Research Protections (ORP). The ORP Animal Care and Use Review Office (ACURO) is responsible for all animal research. The ORP Human Research Protection Office (HRPO) is responsible for all research involving human subjects. ***Exempt human subjects research requires a determination from the PI's institution as well as the ORP at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

Concurrent with the US Army Medical Research Acquisition Activity 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/organizations are included in the Application, then a Certificate of Environmental Compliance for each site will also be requested.

B. Safety Program Documents

The Principal Investigator Safety Program Assurance form will be requested prior to award negotiations. If multiple research sites/organizations are included in the Application, then a Safety Program Assurance form for each site will also be requested.

A Facility Safety Plan will be requested from each research site/organization funded by the award. Specific requirements for the Facility Safety Plan can be found at https ://mrmc.amedd.army.mil/assets/docs/sse/SafetyAppendix093008.pdf. A Facility Safety Plan from a research site/organization may have been received previously and approved by the USAMRMC. A list of organizations that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/assets/docs/SSE/Facility_Safety_Plan_Approved Institutions .pdf.

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the Application is selected for funding (these documents should not be submitted with the Application). The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version the animal use appendix entitled "Research Involving Animals." For guidance on which version of the appendix to use as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid= Research _Protections.acuro _Animalappendix. Allow 2 to 4 months for regulatory review and approval processes for animal studies.

For additional information, send an email with questions to ACURO (ACURO@amedd.army.mil).

D. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

All USAMRMC -funded research involving human subjects and human biological substances must receive a headquarters-level administrative review (HLAR) and be approved by the USAMRMC Office of Research Protections (ORP) in addition to local Institutional Review Boards (IRBs). The ORP is mandated to ensure that all research complies with specific laws and directives governing research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP requirements must be addressed and any changes to the already approved protocol must approved as an amendment 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/index.cfm?pageid=research_protections.hrpo 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. During the regulatory review process for research involving human subjects, the ORP requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the "Guidelines for Investigators" found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo 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.

Documents related to the use of human subjects or human anatomical substances will be requested if the Application is recommended for funding. ***Allow at least 4 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances

can be found at https ://mrmc.amedd.army.mil/index.cfm?pageid=researchprotections.hrpo.

1. Assurance of Compliance: Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection Federalwide Assurance or a DOD Assurance. All awardees (institution listed on the Application, contract, and/or assistance agreement) receiving funds that will support non-exempt human subjects research are considered to be "engaged" in the research and responsible for oversight, even if the research is sub contracted to other institutions.

2. Training: Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction will be required during the regulatory review process.

3. Informed Consent Form: 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 USAMRMC (or the DOD) are authorized to review research records.
- In the event that a separate Health Insurance Portability and Accountability Act (HIPAA) authorization is required, representatives of the USAMRMC must be listed as one of the parties to whom private health information may be disclosed.

4. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980) which are applicable to DOD-sponsored research. 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 Rule 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, cognitively impaired, 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 Phase I and 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.

10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, blood draws, and tissue collections.

Contact HRPO at 301-619-7550 for further clarification regarding applicability of 10 USC 980 to the proposed research project.

5. Medical Monitor Requirement: An independent medical monitor must be identified in the protocol for all greater than minimal risk protocols. A curriculum vitae or biographical sketch and human subjects protection training must be provided. The medical monitor must have no apparent conflict of interest. The medical monitor must not be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. It is acceptable to provide appropriate compensation to the medical monitor for his or her services.

The role of the medical monitor must be described in the protocol and be 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 ORP. The medical monitor may be assigned to discuss research progress with the PI, interview volunteers, consult on individual cases, or evaluate adverse event reports. Medical monitors must promptly report discrepancies or problems to the IRB and the ORP. 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. Research with no physical or psychological risks may be determined to be greater than minimal risk for other reasons (e.g., sensitivity of identifiable data). In these cases, it may be acceptable to employ a "research monitor" to fulfill this role (e.g., someone with an Information Technology background may be appropriate to monitor security of data stored in electronic systems).

6. Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel volunteers.

- **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 will be requested from the Commander of military facilities or units in which recruitment will occur or the study will be conducted. 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. For

greater than minimal risk research, an ombudsman must be employed when conducting group briefings with Active Duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman 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.

- **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.
- **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 and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse, and sexual orientation can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

7. Site Visits: The USAMRMC ORP HRPO conducts random site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

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/index.cfm?_pageid=research protections.hrpo.

8. Protocol Submission Format: The ORP accepts protocol submissions in the format required by the local IRB. To avoid delays in the approval process, PIs should take the ORP guidelines into account when developing protocols for submission to the local IRB.

E. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of "TATRC- Log Number" (e.g., TATRC-#########). If several protocols exist under the same Application, the Secondary Protocol ID number must be designated "TATRC- Log Number-A, B, C, etc" (e.g., TATRC-#########-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health database (see http://prsinfo.clinicaltrials.gov/) click on "Data Element Definitions") are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds per US Public Law 110-85.

APPENDIX 6
ACRONYM LIST

ACURO	Animal Care and Use Review Office
ADP	Automated Data Processing
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
CAGE	Commercial and Government Entity
CCR	Central Contractor Registry
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
COI	Conflict of Interest
CRADA	Cooperative Research and Development Agreement
DFARS	Department of Defense Federal Acquisition Regulation Supplement
DHHS	Department of Health and Human Services
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Number System
EIN	Employer Identification Number
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
MB	Megabyte
MPEG	Moving Picture Experts Group
MTF	Medical Treatment Facility
OMB	Office of Management and Budget
ORP	Office of Research Protections
PDF	Portable Document Format
PI	Principal Investigator
POC	Point of Contact
SOW	Statement of Work
TIFF	Tagged Image File Format
TIN	Tax Identification Number
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