Fiscal Year 2005 (FY05)
Department of Defense (DOD)
Peer Reviewed Medical Research Program (PRMRP)
Supplement to the Current US Army Medical Research and Materiel Command (USAMRMC)
Broad Agency Announcement (BAA)

This document is a supplement to the current USAMRMC BAA and is self contained. **All guidelines contained in this FY05 Supplement supersede current BAA instructions.**

I. OVERVIEW OF THE FY05 PRMRP

The USAMRMC has been directed to conduct innovative research and development with specific goals and endpoints. The Defense Appropriations Act of 2005 (Public Law 108-622) provides $50 million (M) to fund peer-reviewed medical research. As the executive agent for the PRMRP, the USAMRMC has assigned this program to the Office of Congressionally Directed Medical Research Programs (CDMRP). Based on congressional guidance published in previous fiscal years' Defense Appropriations Acts, the PRMRP was established to provide support for military health-related research of clear scientific merit. Thus, proposals submitted to the FY05 PRMRP must be scientifically meritorious and must clearly explain the military relevance of the proposed efforts.

Proposals will be assessed based on how they complement existing DOD research. The submission of a Letter of Intent (LOI) is required to facilitate this objective (see page 7). Applicants are expected to survey the peer-reviewed literature to avoid duplication of previously described research efforts, including those previously supported by the DOD and/or its investigators. An additional source containing documentation of previously accomplished research supported by the DOD can be found at the Defense Technical Information Center website at http://www.dtic.mil. To help identify DOD specific areas of interest within each FY05 PRMRP research topic area listed on page 4, applicants are encouraged to review ongoing research described on the following websites:

- http://www.usamraa.army.mil
- http://cdmrp.army.mil
- http://www.arl.army.mil
- http://www.onr.navy.mil
- http://www-nehc.med.navy.mil
- http://www.nhrc.navy.mil
- http://www.nrl.navy.mil
- http://www.afrl.af.mil
- http://www.brooks.af.mil
- http://www1.va.gov/resdev
- http://www.acq.osd.mil

Proposals are being solicited from agencies of local, state, and federal governments; educational institutions; nonprofit organizations; and private industry. Since military relevance is a critical programmatic review criteria, applicants are strongly encouraged to collaborate and integrate their projects with military and/or Veterans Affairs (VA) research laboratories and programs.

II. GENERAL INFORMATION

A. Electronic Submission: All proposals and supporting documentation must be submitted electronically to the FY05 PRMRP. Proposals must be submitted on the site listed below. Proposals and letter of intents submitted to any other USAMRMC website will not be accepted. **No paper copies will be accepted.**

B. Website to Access Application Package: Proposals must be submitted electronically at **https://cdmrp.org/index.cfm**. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact CDMRP as indicated in Subsection II.C.

C. Questions Related to Electronic Submission (eReceipt): Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission or the process of electronic submission. Help desk contact information is:

Phone:	301-682-5507
Website:	https://cdmrp.org/index.cfm (the proposal submission website)
E-mail:	help-proposals-cdmrp@cdmrp.org

D. For Non-eReceipt-Related Questions (For example: Questions regarding Certifications and Assurances for Assistance Agreements), Please Contact:

Ms. Patricia Evans
USAMRAA
820 Chandler Street
Fort Detrick, MD 21702-5014
301-619-7354

E. Critical Steps for Successful File Submission

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- Proposal contacts must be submitted prior to submission of the proposal.
- The e-mail address of a Contract Representative from the applicant's Sponsored Programs Office (or equivalent) must be included in "Proposal Contacts."
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- The Contract Representative from the applicant's Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time March 8, 2005 deadline.

- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF (Portable Document Format) file prior to upload.
- Some items included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents including figures should be scanned at a resolution of 300-400 dpi (dots per inch) or less.
- Budget information includes the Detailed Cost Estimate and Justification Form. Budget information must be uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.
- The Office of Research Protections (ORP) and the US Army Medical Research Acquisition Activity (USAMRAA) documents are required at submission (see Subsections IV.F and IV.G of this Supplement). Regulatory documents must be uploaded under the "Required Files" tab, and the USAMRAA documents must be uploaded under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system.

F. Cost Sharing: At a minimum it is expected that institutions will cost share for major equipment. Please see full details in Subsection IV.E, under **Detailed Cost Estimate and Justification Form Instructions**.

G. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

The following will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed Cost Estimate is missing.
- Proposal is incomplete after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages exceeding the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the Government, any material submitted after the submission deadline will not be forwarded for peer review.

H. Award/Regulatory Approval: Please see Subsection IV.F for specific human subjects and animal use requirements as appropriate.

Collaborating and subcontracting institutions at which proposal-related research is planned must be identified, and letters of collaboration and/or evidence of subcontract must be provided with the proposal at the time of submission (Please see Subsection IV.D.2). Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without express written permission from the USAMRMC ORP. USAMRMC ORP will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

III. AWARD INFORMATION

A. Research Topic Areas (Note: Your proposal must specifically and clearly address one of the topic areas listed below for consideration.): Failure to specifically and thoroughly address a given topic area will result in a negative peer and programmatic review evaluation.

- Acellular Human Tissue Matrix Research
- Amyotrophic Lateral Sclerosis
- Alcoholism Research
- Anti-radiation Drug Development
- Autism
- Autoimmune Diseases Such as Scleroderma and Sjogren's Syndrome
- Blood-related Cancer Research
- Childhood Asthma
- Chronic Pain Research
- Conjugate Vaccines to Prevent Shigellosis
- Diabetes Research
- Duchenne's Disease Research
- Lung Cancer Screening[1]
- Lupus and Lupus-Biomarker Research
- Epilepsy Research
- Interstitial Cystitis
- Military Relevant Disease Management especially Acinetobacter baumannii infections, obesity research, and smoking cessation[1]
- Orthopaedic Extremity Trauma Research
- Osteoporosis and Bone Related Diseases Research
- Padget's Disease (sic)
- Post-Traumatic Stress Disorders
- Social Work Research
- Volume Angio CAT (VAC) Research

[1]Topic Area added by Health Affairs

Please note that the Government reserves the right to reassign the proposal's topic area or to disqualify the proposal if the research has no relevance to currently advertised PRMRP topic areas.

B. Award Mechanisms (Select only one of the four award mechanisms listed below):

1. Investigator-Initiated Research: This traditional award mechanism is intended to support basic or clinical military relevant research studies focused on a target area solicited in this FY05 Supplement to the current BAA.

2. New Program Project: This award mechanism is intended to establish a multidisciplinary program in a target area solicited in this FY05 Supplement to the current BAA.

3. Existing Program Project: This award mechanism is intended to support the continuation of a multidisciplinary program in a target area solicited in this FY05 Supplement to the current BAA.

4. Advanced Technology Development: This award mechanism is intended to support the advanced development of a military health-related product or technology in a target area solicited in this FY05 Supplement to current BAA.

C. General Budget Guidelines: Budget requests are an important component of the peer and programmatic review evaluation processes. Budget guidelines and award lengths for each award mechanism offered by the FY05 PRMRP are shown in the following table. The maximum budget recommendations are for the total budget, inclusive of direct and indirect costs. Budgets greater than the specified funding limit for that mechanism will be negatively considered (see table below). The PRMRP expects to fund up to three Advanced Technology Awards and up to two Program Project Awards (including New and Existing) for the FY05 program.

Award Mechanism	Recommended Maximum Budget	Period of Performance
Investigator-Initiated Research	$1M	4 years
Program Project (New or Existing)	$2M	4 years
Advanced Technology	$3M	4 years

IV. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this FY05 Supplement to the current BAA.

The Principal Investigator (PI) is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A LOI is generated when a draft of Part 1 of the Proposal Information is saved. LOIs will be used to aid in determining proposal submission intent.
- **Proposal Contacts:** Contact information for both the PI and the Contract Representative is required to complete the proposal submission process.
- **Statement of Work (SOW), Structured Technical Abstract, and Military Relevance Statement:** The SOW, Technical Abstract, and Military Relevance Statement are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF file under the "Required Files" tab.
- **Verification Letters for Access to Military Recruits or Subjects and Materials:** These letters of support should be uploaded as part of the proposal, if applicable.
- **PI Past Performance on CDMRP Awards:** This one-page summary should be uploaded as part of the proposal, if applicable.
- **Human Subjects Research Review Criteria:** This three-page summary should be uploaded as part of the proposal, if applicable.
- **Budget Information:** The budget information is uploaded as a PDF file under the "Required Files" tab.
- **Federal Agency Financial Plan Requirements:** The Federal Agency Financial Plan must be included as part of the budget information, if applicable.
- **Regulatory Documents:** These documents are each uploaded as separate PDF files under the "Required Files" tab.

The Contract Representative (or equivalent) from the applicant's institution is responsible for the following:

- The Contract Representative's contact information profile must be completed prior to electronic approval of all proposal components.
- **USAMRAA Documents:** The institution's currently negotiated "Rate Agreement", "Certifications and Assurances for Assistance Agreements", and the "Representations for Assistance Agreements" are to be uploaded as separate PDF files under the Contract Representative "My Profile" tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal Information, SOW, Structured Technical Abstract, Military Relevance Statement, Proposal, PI Past Performance on CDMRP Awards, Human Subjects Research Review Criteria, Budget Information, Federal Agency Financial Plan, Transition Plan for the Advanced Technology Funding Mechanism, and Regulatory Documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time March 8, 2005. The eReceipt system will **not**

accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time March 8, 2005 deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described at https://cdmrp.org/proposals. The Proposal Information must include the e-mail address of a representative from the applicant's Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution.

- **Letter of Intent:** All applicants considering submission of a proposal in response to this FY05 Supplement to the current USAMRMC BAA are expected to submit an electronic LOI by **February 8, 2005**. The LOI should include a brief description of the military relevance of the proposed project. To accomplish this, the applicant should complete Part 1 of the Proposal Information section athttps://cdmrp.org/proposals, then save the information by clicking on the "Save and Forward Letter of Intent" button. This information may be changed at any time until the applicant submits the final Proposal Information (by clicking on the "Submit Final" button).

C. SOW, Abstracts, and Military Relevant Statement

1. SOW: 11,400-Character Limit, Including Spaces (Approximately Two Pages): The SOW is captured as a data field under the "SOW/Abstracts" tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW, or electronically cut and paste it from a word processing application into the data field.

The SOW is a concise restatement of the research proposal that outlines and establishes the PI's performance expectations and timeline for which the USAMRMC will provide financial support. Although some allowance is made for problems encountered and uncertainties that are part of research, the PI is expected to meet the provisions and milestones in the SOW. Failure to meet deliverables as defined by tasks may result in withdrawal of funds.

The SOW should be a series of relatively short statements that outline step-by-step how each of the major goals or objectives of the proposed research/services will be accomplished. **The SOW should only describe work for which funding is being requested by this proposal**. As appropriate, the SOW should:

- Describe the work (deliverables) to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the period of the proposed effort;
- Indicate the number of research subjects (animal or human) and/or anatomical samples projected or required for each task;
- Identify methods;

- Identify outcomes, products, and deliverables for each phase of the project; and
- Include the following information for each study site/subaward site that will be actively participating in the study:
    - Institution name,
    - Institution address,
    - Co-PI name, and
    - Animal or human use at this site.

A sample SOW can be shown by clicking on Sample Statement of Work.

2. Technical Abstract: A one-page (5,700-character limit, including spaces) structured technical abstract must be submitted as part of the Proposal Information. A sample technical abstract can be found at https://cdmrp.org/samples.cfm. The abstract is important to both the peer and programmatic review process. Programmatic review is conducted by the Joint Programmatic Review Panel (JPRP) that is composed of a team of federal and military scientists and clinicians. The programmatic review process is based on the JPRP's 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. The abstract must be submitted as a data field under the "SOW/Abstracts" tab of the CDMRP eReceipt system. Applicants can either type in their abstract, or electronically cut and paste it from a word processing application into the respective data field. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Thus, proprietary or confidential information should not be included in the abstract.

Abstract Guidelines: 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.

Use the outline 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 health outcomes.

3. Military Relevance Statement: At the "SOW/Abstracts" tab of the CDMRP eReceipt system in the "**Public Abstract**" data field, provide a statement (5,700-character limit, including spaces) describing the military relevance of your proposal and the appropriateness of your research to the selected topic area. Also describe how this research will benefit the military if the proposed research is successful. In cases where the proposed study involves military recruits or subjects, military controlled study materials, databases, and/or restricted facilities (e.g., biological or chemical containment facilities), clearly identify the military collaborations/subawards/study sites and contributions to the study. The appropriate verification letter(s) of access to military troops or subjects and materials can be uploaded as part of the proposal if applicable (see Subsection IV.D.2).

D. Proposal

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt system (https://cdmrp.org). Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this section must be followed carefully.

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

- **Type Font:** 12 point, 10 pitch
- **Type Density:** No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- **Spacing:** Single-spaced between lines of text, no more than five lines of type within a vertical inch
- **Margins:** Minimum of 0.5-inch 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.
- **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 (approximately 19 cm x 25.5 cm)

2. Sections of the Proposal (Note: These sections should be scanned into one PDF file before uploading):

- **Research Proposal Cover Page:** Use the instructions below and the Research Proposal Cover Page Form.

  A completed Research Proposal Cover Page must be the first page of the full proposal. The Cover Page must contain the information listed below. A suggested format is provided.

  a. Name and Address of Offeror: The full name and address of the organization or institution submitting the proposal should be supplied for this item.

  b. Proposal Title: Insert title of research proposal not to exceed 120 characters.

  c. Estimated Cost: Total cost to complete research effort **(including direct and indirect costs).**

  d. Proposed Start Date: Earliest date PI believes work could begin (at least 6 months from the submission date).

  e. Proposed Duration: Number of years to complete research effort and complete final reports.

  f. Proposal Valid Until: Allow a minimum of 9 months from the date of submission.

  g. PI's Organization: The name of the organization where the PI is employed.

  h. PI's Information: Name, address, e-mail, phone, and fax.

  i. Administrative Representative's Information: Name, address, e-mail, phone, and fax.

  j. Alternate PI Information: Name, phone, and e-mail.

  k. Alternate Administrative Representative Information: Name, phone, and e-mail.

  l. Authorized Representative's Information: Name, title, signature, and date.

- **Table of Contents/Checklist:** Prepare a Table of Contents/Checklist, with page numbers, by clicking on Table of Contents/Checklist Form. Number all pages consecutively at the bottom center, beginning with the Research Proposal Cover Page.
- **Proposal Relevance Statement: One-page limit.** Start the Proposal Relevance Statement on a new page. Applicants should state explicitly (within the one-page limit) the proposal's relevance to the selected topic area and its impact on health outcomes.

- **Transition Plan for the Advanced Technology Development Funding Mechanism: One-page limit.** Start the Advanced Technology Development Funding Mechanism Transition Plan on a new page. Applicants **must** describe the Advanced Technology Development Transition Plan for submissions to the Advanced Technology Development award mechanism. The plan should address the methods and strategies proposed to provide continuity for the development/funding/military acquisition of the product beyond PRMRP funding. The transition plan will be reviewed at programmatic review. Failure to submit a transition plan may result in a lower priority rating during programmatic review.
- **Main Body of Proposal: 25-page limit.** Start this section on a new page. **This section is limited to 25 pages inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal**. **Note that additional information within the proposal directing reviewers to web sites containing additional information about this research will not be considered for review.** The following general outline should be followed when preparing the proposal:

  a. **Hypothesis:** State the hypothesis to be tested and the expected results;

  b. **Technical Objectives:** State concisely the question to be answered by each research objective;

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

  d. **Military Relevance:** 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;

  e. **Public Purpose:** If appropriate, provide a concise, detailed description of how this research project will benefit the general public;

  f. **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; and

  g. **Investigator's Qualifications:** By submitting a proposal and accepting an award, the organization is certifying that the investigator's credentials have been examined and verifying that the investigator is qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed.

- **Appendices:** Page limits apply to certain appendices; refer to each section below for specific details.
- **Acronym and Symbol Definitions: One-page limit.** Provide a glossary of acronyms and symbols that might not be familiar to reviewers who are not current in the proposal's research area.

- **Bibliography: No page limit.** 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.
- **Biographical Sketches: Three-page limit per individual.** Biographical sketches should be included for the participants at the applicant institution, participants at the collaborating institution, and each of the proposed key personnel, including all collaborating investigators. These documents are a critical component of the screening process. The Biographical Sketch form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.
- **Existing/Pending Support: No page limit.** List the title, time commitments, supporting agency, and level of funding for all existing and pending research projects involving the PI and key personnel. Provide justification for USAMRMC support and interest where the projects overlap or parallel. To enable a proper determination of the offeror's past performance, either for use in a technical evaluation or for determination of the necessary level of preaward survey, it is requested that synopsis of awards be prepared on similar or related effort for the past 3 years, including:
  - **a.** Specifics on each award, including types and dates of performance;
  - **b.** The name and address of the Procuring Contracting/Grants Officer; and
  - **c.** The negotiated price, and the final cost to the Government, with reasons for the variance.
- **Facilities/Equipment Description: No page limit.** 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 whether 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.
- **Questionnaires, Survey Instruments, or Clinical Protocols: No page limit.** If available at the time of submission, questionnaires, survey instruments, or clinical protocols should be appended. Additionally, append an appropriately titled page listing the documents you have included in this section.
- **Publications and/or Patent Abstracts: Five-document limit.** Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.
- **Letters of Collaboration and Joint Sponsorship: No page limit.** The first item in this section must be a list of all the items included in this section. Provide letters of support from any collaborating individuals or institutions in this section of the proposal. All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted

proposal. Please note that if the proposed human subject research will be conducted at multiple sites, a study coordinator is recommended.

- **Verification Letters for Access to Military Recruits or Subjects and Materials:** In cases where the proposed studies involve military recruits or subjects, military controlled study materials, databases, and restricted facilities (e.g., biological or chemical containment facilities), a letter of support signed by the responsible commander (Installation, Troop, or Institute Commander) confirming access to recruits/military subjects and military materials is required. Additionally, a military collaborator is recommended for research involving military troops. These letters of support should be uploaded as part of the proposal at the time of proposal submission (no later than **5:00 p.m. Eastern time March 8, 2005**). If letters cannot be submitted with the proposal, an electronic copy (in a format readable by IBM-compatible versions of Microsoft Office or Adobe Acrobat) on a formatted disk must be postmarked to the address listed below by **June 17, 2005**. Failure to submit such a letter (if applicable) will result in proposal rejection at programmatic review.

  Attention: Dr. Barbara Terry-Koroma
  US Army Medical Research and Materiel Command
  1077 Patchel Street
  Fort Detrick, MD 21702-5024

- **PI Past Performance on CDMRP Awards: One-page limit.** In cases where the PI has previously been funded through the CDMRP, a one-page description is required that addresses the current state of the research. This includes whether the tasks outlined in the SOW have been accomplished and/or are progressing in a timely fashion. Likewise, if the PI has experienced delays in accomplishing these tasks, he or she may explain the reasons why these goals have not been met. Please note that the Program Office will be providing past performance data gleaned from past annual reports to the JPRP during Programmatic Review. Please note that this the requirements for this summary are different from what is expected under existing/pending support information in that is only applies to CDMRP awards.

- **Human Subjects Research Review: Three-page limit.** If the proposed study involves human subjects, the PI is required to submit a three-page summary describing key aspects of human subjects research that will be conducted. In particular, the following points must be addressed:

  Objective of clinical study
  - Briefly describe the purpose/research objective of the clinical study.

  Brief summary of procedure with timeline
  - Describe how the key study variables will be measured
  - Describe the timeline for required study subject visits and list the procedures to be performed at each.
  - Briefly describe the procedures for data and specimen collection, analysis, and evaluation.

Proposed subject recruitment process

- Describe the target population from which study subjects will be recruited.
- Provide a scientific rationale for the target sample size.
- Describe the subject recruitment process, including who will identify potential subjects and how they will be recruited.

Proposed consent process

- Describe the consent process, including when and where the consent interview will take place and the time available for the subjects to consider participation and ask questions.
- Describe the circumstances under which consent from a legally authorized representative may be required and the process through which it will be obtained.
- Describe any unusual consent related issues pertaining to this study.

Risk and intent to benefit

- Describe the most prominent risks involved in study participation (physical, psychological, legal, social, economic) and the measures that will be taken to minimize and/or manage them.
- Describe the potential benefits to individual study subjects and to society.
- Describe the intent to benefit for those subjects unable to provide their own consent, if applicable.

Description of the safety monitoring procedures that will be used in the protocol

- If the study is greater than minimal risk, name the medical monitor and describe his/her role.
- Define adverse events for this study.
- Describe the process for reporting serious and unexpected adverse events.

Proposed plan for study subject confidentiality

- Describe the strategy for protecting the privacy and confidentiality of research subjects and study data/records.
- Describe any expected circumstances under which complete confidentiality cannot be guaranteed (e.g., active duty personnel participating in intramural research).

Status of FDA submission (IND, IDE, NDA, PMA, 510K, etc.), if applicable

- If the clinical study involves the use of a drug, biologic, or device not yet approved for marketing by the FDA or not yet approved for the indication addressed in the study, state the status of the applicable FDA submission.

- Identify who will serve as the Clinical Trial Sponsor.
- Indicate whether the institution has previous experience working with the FDA in developing and conducting clinical trials and provide the location of the regulatory staff who will oversee FDA submissions. Additionally, insure that there is a provision for FDA –required clinical monitoring of the clinical trial.

E. Budget Information: Budget information includes the detailed cost estimate and justification form, and Federal Agency Financial Plan. Budget information must be uploaded under the "Required Files" tab of the CDMRP eReceipt system prior to the receipt deadline of **5:00 p.m. Eastern time March 8, 2005**. **(Note: Upload a new PDF file for this section).** The budget information will be forwarded to both tiers of review.

Detailed Cost Estimate and Justification Form Instructions: An estimate of the total research project cost, with a breakdown of direct and indirect costs by category and year, must accompany each formal proposal (please click on Detailed Cost Estimate Form). **Failure to use this budget form may impact negatively on proposal review.** All costs must be entered in U.S. dollars. Recipients performing outside of the United States should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used. Multiple year proposals are encouraged to cover the total estimated duration of the project. Incremental funds may be provided by USAMRMC for effort performed during each federal fiscal year. Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil) Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions.
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments.

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.

1. **Personnel**

   a. **Name:** Starting with the PI, list the names of all participants who will be involved in the project during the proposed budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff.

b. Role on Project: Identify the role of each individual listed on the project. Describe his or her specific functions in the "Justification" section of the Detailed Cost Estimate form.

c. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the "Justification" section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

d. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project. 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.

e. Percentage of Effort on Project: The qualifications of the PI and the amount of time that they and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

f. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

g. Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization for all sponsors. Documentation to support the fringe benefits should be provided.

h. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

2. Consultant Costs: Regardless of whether funds are requested, provide 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.

3. Major Equipment

a. It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

b. An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 2 years and an acquisition cost of $5,000 or more per unit. The basis for the cost of each item of permanent equipment included in the budget must be disclosed.

(1) Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.

(2) Historical Cost: Identify vendor, date of purchase, and whether cost represented lowest bid. Include release(s) for not soliciting current quotes.

(3) Estimate: Include rationale for estimate and reasons for not soliciting current quotes.

(4) Special test equipment to be fabricated by the contractor for specific research purposes and its cost.

(5) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.

(6) 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.

(7) 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.

(8) 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.

c. It is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

4. Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than $1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

5. Travel Costs: List the number of trips, number of people per trip, the destinations, and the purpose for all proposed travel annually. Estimate round trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the specific meeting and purpose. Usually, no more than one trip to a scientific meeting for one person, usually the PI, is funded.

6. Research-Related Subject Costs: Itemize 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.

7. Other Direct Costs: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

8. Consortium/Subaward Costs: A description of services or materials that are to be awarded by subcontract or subgrant is required. The following information must be provided on subawards totaling $10,000 or more:

a. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);

b. Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;

c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;

d. The proposed acquisition price; and

e. The offeror's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $500,000 and the offeror is a large business or an educational institution (other than Historically Black Colleges and Universities/Minority Institutions [HBCU/MI]), the contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

9. 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 with a statement identifying whether the proposed rates are provisional or fixed. A copy of the negotiated rate agreement should be provided with the proposal. If negotiated forecast rates do not exist, provide sufficient detail regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions. Commercial firms can also visit http://www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established.

As a minimum, submission should identify:

a. All individual cost elements included in the forecast rate(s);

b. The basis used to prorate indirect expenses to cost pools, if any;

c. How the rate(s) was calculated; and

d. The distribution basis of the developed rate(s).

10. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should equal the amount entered on the Proposal Cover Page.

11. Fixed Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a profit or fee is negotiated, the award will be a contract. Any fixed fee applied to the research project must be listed, and a claimed Facilities Capital Cost of Money supported by **DD Form 1861** (http://www.dior.whs.mil/icdhome/forms.htm) must be submitted with the full proposal.

12. Justification (third page of the Detailed Cost Estimate form): Clearly justify each item in the budget under the "Justification" section of the Detailed Cost Estimate form.

Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. It is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

Note the cost of preparing proposals in response to this BAA supplement is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and OMB Circulars A-21 and A-122.

13. Federal Agency Financial Plan Requirements: (Note: Start the plan on a new page at the end of the Budget Information section). The Federal Agency Financial Plan must be uploaded as part of the budget information prior to the receipt deadline of **5:00 p.m. Eastern time March 8, 2005**. Proposals from federal agencies are **expected to** provide a plan delineating how all funds will be obligated by September 30, 2006, and how funds will be available to cover research costs over the entire award period. The plan is **expected to** include mechanisms used to ensure carry-over of funds between years such as administrative agreements with nonfederal institutions, foundations, and universities. Failure of federal agencies to include a financial plan to handle one-time receipt of funds dispensed over multiple years will result in a lower priority at programmatic review.

Note: The maximum budget is inclusive of direct and indirect costs. Budgets greater than $1M for Investigator-Initiated Research Awards, $2M for Program Project

Awards (both New and Existing), and $3M for Advanced Technology Awards will be negatively considered.

F. Regulatory Requirements: Completed and signed copies of each of the documents listed below must be uploaded as separate PDF files using the "Required Files" tab of the CDMRP eReceipt system by the **March 8, 2005** receipt deadline. **Please note that the Government reserves the right to withdraw a funding offer issued for any proposal that fails to comply with the deadlines indicated.**

It is required that all IND, IDE, or FDA approvals be obtained prior to January 31, 2006 if the entire study relies on an investigational agent. Exceptions will be made for those studies which will rely on generating pre-clinical data for IND, IDE, or FDA approval in earlier tasks of the project. Please note that no award will be made until these approvals are obtained. If the IND, IDE, or FDA approval is not received by January 31, 2006, the Government reserves the right to not fund the award.

1. Certification of Environmental Compliance: This form can be found at https://cdmrp.org/programAnnouncements.cfm. Information regarding environmental compliance must be provided with the full proposal. The form must be completed by the environmental compliance officer for each facility where proposal-related laboratory research is planned, and submitted by the receipt deadline.

2. Safety Program Documents: A Facility Safety Plan and the Facility Safety Manager Assurance must be completed for each facility where proposal related laboratory research is planned and submitted by the receipt deadline if not already approved and on file at https://mrmc.detrick.army.mil/. The appendix describing this plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc. Likewise, the PI Safety Assurance must be completed by the responsible investigator at each facility where proposal-related laboratory research is planned, and submitted by the receipt deadline.

Completed and signed copies of each of the documents listed below must be uploaded as separate PDF files using the "Required Files" tab of the CDMRP eReceipt system within 2 weeks of receipt of a funding letter, or as indicated.

3. Research Involving Animals: The appendix listing specific documentation required for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc. All pertinent issues relating to the use of animals in the proposed research including assurances and certifications (PI Animal Safety Assurance, American Association for Accreditation of Laboratory Animal Care [AAALAC] accreditation, U.S. Department of Agriculture [USDA] letter of inspection, Public Health Service [PHS] Animal Welfare Assurance), and a description of the animal research protocol must be addressed for each facility where animal research is planned and submitted within 2 weeks of receipt of a funding letter. Institutional Animal Care and Use Committees (IACUC) approval of the animal research protocol will be required during negotiation of the award and prior to the start of animal research.

4. Research Involving Human Anatomical Substances: A Claim of Exemption form and the consent form indicating subjects were informed that specimens may be used for research purposes (if applicable) must be completed by the responsible investigator at each institution where human anatomical substance research is planned and submitted within 2 weeks of receipt of a funding letter. This form is found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc. The Institutional Review Board (IRB) declaration of exemption will be required during award negotiation and prior to the start of human anatomical substance research.

5. Research Involving Human Subjects: The three-page summary describing the proposed human subjects research (see Subsection IV.D.2 of this Supplement) must be submitted by the proposal submission deadline. The clinical protocol, consent form, case report form, advertisement materials, IRB approval, conflict of interest forms completed by all study personnel, and documentation of formal Human Subject Research Training for all study personnel will be required during award negotiation and prior to the start of human subjects research. The appendix describing human subject use requirements can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc.

In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances or cadavers, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Office of Research Protections (ORP) (formerly Regulatory Compliance and Quality). The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

- Intent to Benefit. Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 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 prior to 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 DOD-sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators should be aware that this law makes placebo-

controlled clinical 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.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc.

An informed consent form template can be located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

G. USAMRAA Requirements: The most current version of the documents listed below must be uploaded by the Contract Representative from the applicant's Sponsored Programs Office (or equivalent). These documents must be uploaded as separate PDF files using the Contract Representative "My Profile" tab of the CDMRP eReceipt system by the **March 8, 2005** receipt deadline:

1. A copy of the institution's negotiated Rate Agreement

2. Certifications and Assurances for Assistance Agreements: This form can be found at https://cdmrp.org/programAnnouncements.cfm.

3. Representations for Assistance Agreements: This form can be found at https://cdmrp.org/programAnnouncements.cfm.

H. Submission and Notification Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's Sponsored Programs Office (or equivalent) by the deadline. Unlike other proposals submitted under the current BAA, which can be submitted throughout the year, **FY05 PRMRP proposals must be submitted electronically by 5:00 p.m. Eastern time on March 8, 2005, or they will not be considered for review.** The eReceipt system will **not** accept data entry, file upload, or approvals submitted after the 5:00 p.m. Eastern time deadline.

The general timeline for the FY05 PRMRP is:

Online Letter of Intent:	Expected by **February 8, 2005**
Online Proposal Information:	**Prior to proposal submission**
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time March 8, 2005**
ORP and USAMRAA Documents:	**5:00 p.m. Eastern time March 8, 2005**
Peer Review:	**May 2005**
Programmatic Review:	**July 2005**
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review (if needed)
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Between **October 2005 and September 2006**

V. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit and direct relevance to military health, as well as other programmatic criteria and goals. **The proposal evaluation criteria listed below are specific to the FY05 PRMRP and supersede any evaluation criteria that are listed in the current BAA.**

2. Peer Review: Peer review is conducted by panels of scientists organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals to the topic areas based on the review criteria published for each award mechanism. The peer review summary statement is the main product of scientific peer review. Each statement includes the applicant's structured technical abstract, the peer review score, proposal relevance statement, and an evaluation of the project as assessed by the peer reviewers according to the above evaluation criteria. Summary statements (not full proposals) are forwarded to the next stage of the review process, programmatic review.

Specific peer review criteria are provided below for Investigator-Initiated Research, New Program Project, Existing Program Project, and Advanced Technology Development Awards. **You must identify the award mechanism to which you are applying**. Selection of two or more award mechanisms will result in disqualification of your submission.

a. <u>Investigator-Initiated Research Awards:</u> The following review criteria supersede any listed in the current BAA; they serve as the sole peer review criteria for Investigator-Initiated Research proposals.

- **Research Strategy and Objectives:** Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed, appropriate, and well integrated to the aims of the project? Is the research more than a slight extension or repeat of currently funded research? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics?
- **Impact:** Does the proposal address an important problem and directly address the selected FY05 PRMRP topic area? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Are the results likely to be published in the peer-reviewed scientific literature?
- **PI and Key Personnel Qualifications:** Is the PI appropriately trained and well suited to guide this project? **Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project?** Is the work

proposed appropriate to the experience and expertise of the PI and other researchers (if any)? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)? If the PI has been funded by the CDMRP in the past, has sufficient progress been made in the funded project? If not, are the reasons why presented adequately (as described in the PI past performance summary)?

- **Facilities:** Is the scientific environment appropriate for the proposed research? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support provided with the proposal?
- **Human Subjects Research Review (if applicable):** Has the PI adequately described the objective as well as the procedure of clinical study? Are the proposed recruitment process, the consent process, and the plan for study subject confidentiality reasonable? Does the PI adequately explain the risk and intent to benefit from findings of the study? When applicable, does the PI provide a status FDA submission(s) (IND, IDE, NDA, PMA, 510K, etc.). Does the PI sufficiently explain what safety monitoring procedures will be used in the protocol?
- **Budget:** Is the budget well justified and appropriate for the research proposed? Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultant, equipment costs, or the scope of the research (time or aims)? Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project?

b. **New Program Project Awards:** The following review criteria supersede any listed in the current BAA; they serve as the sole peer review criteria for New Program Project proposals.

- **Research Strategy and Objectives:** Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed, appropriate, and well integrated to the aims of the project? Is the research more than a slight extension or repeat of currently funded research? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Are all component research projects well conceived and likely to lead to important findings or become the basis for future peer-reviewed funded research? Are pilot projects (if applicable) well conceived and likely to lead to subsequent fully developed projects?
- **Impact:** Does the proposal address an important problem and directly address the selected FY05 PRMRP topic area? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Are the results likely to be published in the peer-reviewed scientific literature? If applicable, what is the potential impact of the training program in the field addressed by the proposal (e.g., in increasing the number of new investigators in the field)?

- **PI and Key Personnel Qualifications:** Does the PI have the training and expertise to oversee the multidisciplinary research of the program? **Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project?** Is the work proposed appropriate to the experience and expertise of the PI and other researchers (if any)? If an oversight or advisory committee is involved, does it have the appropriate background to provide sufficient guidance? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)? If the PI has been funded by the CDMRP in the past, has sufficient progress been made in the funded project? If not, are the reasons presented adequately (as described in the PI past performance summary)? Have multidisciplinary collaborations been developed that will support the goals of the program? Have letters been submitted to demonstrate support of the multidisciplinary collaborations?
- **Facilities:** Is the scientific environment appropriate for the proposed research? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support provided with the proposal?
- **Human Subjects Research Review (if applicable):** Has the PI adequately described the objective as well as the procedure of clinical study? Are the proposed recruitment process, the consent process, and the plan for study subject confidentiality reasonable? Did the PI provide a statement confirming human subject research to be funded by the DOD award? When applicable, does the PI provide a status FDA submission(s) (IND, IDE, NDA, PMA, 510K, etc.). Does the PI sufficiently explain what safety monitoring procedures will be used in the protocol?
- **Budget:** Is the budget well justified and appropriate for the research proposed (including core functions or equipment)? Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultant, equipment costs, or the scope of the research (time or aims)? Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project? Is there a description of how the facility, the program, and investigators will share costs?
- **Focus and Integration:** Does the central theme of the program involve a specific and important medical condition, injury, or disease process related to the selected FY05 PRMRP topic area? Is there a clear link between the individual research projects, the theme of the program, the training program (if applicable), and the collaborations? If the program includes multiple approaches such as basic, animal, human subjects, and/or rehabilitation research, are the components well integrated? Is the proposal well written, with all the components of the program including the core facility (if applicable) clearly described (including their integration) and justified?

c. <u>Existing Program Project Awards:</u> The following review criteria supersede any listed in the current BAA; they serve as the sole peer review criteria for Existing Program Project proposals.

- **Research Strategy and Objectives:** Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed, appropriate, and well integrated to the aims of the project? Is the research more than a slight extension or repeat of currently funded research? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Are all component research projects well conceived and likely to lead to important findings or become the basis for future peer-reviewed funded research? Are pilot projects (if applicable) well conceived and likely to lead to subsequent fully developed projects?
- **Impact:** Does the proposal address an important problem and directly address the selected FY05 PRMRP topic area? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field? Are the results likely to be published in the peer-reviewed scientific literature? If applicable, what is the potential impact of the training program in the field addressed by the proposal (e.g., in increasing the number of new investigators in the field)?
- **PI and Key Personnel Qualifications:** Does the PI have the training and expertise to oversee the multidisciplinary research of the program? **Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project?** Is the work proposed appropriate to the experience and expertise of the PI and other researchers (if any)? If an oversight or advisory committee is involved, does it have the appropriate background to provide sufficient guidance? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)? If the PI has been funded by the CDMRP in the past, has sufficient progress been made in the funded project? If not, are the reasons presented adequately (as described in the PI past performance summary)? Have multidisciplinary collaborations been developed that will support the goals of the program? Have letters been submitted to demonstrate support of the multidisciplinary collaborations?
- **Facilities:** Is the scientific environment appropriate for the proposed research? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support provided with the proposal?
- **Human Subjects Research Review (if applicable):** Has the PI adequately described the objective as well as the procedure of clinical study? Are the proposed recruitment process, the consent process, and the plan for study subject confidentiality reasonable? Does the PI adequately explain the risk and intent to benefit from findings of the study? When applicable, does the PI provide a status FDA submission(s) (IND, IDE, NDA, PMA, 510K, etc.). Does the PI sufficiently explain what safety monitoring procedures will be used in the protocol?

- **Budget:** Is the budget well justified and appropriate for the research proposed (including core functions or equipment)? Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultant, equipment costs, or the scope of the research (time or aims)? Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project? Is there a description of how the facility, the program, and investigators will share costs?
- **Current Status of the Program:** Is a brief description of the current personnel, facilities, and equipment given, including identifying which components will be continued from prior years? If applicable, have changes to the initial program plan and the rationale for changes been articulated? Is there evidence of continued administrative support for the program? If applicable, have recommendations and/or reports from any advisory committees been submitted?
- **Focus and Integration:** Does the central theme of the program involve a specific and important medical condition, injury, or disease process related to the selected FY05 PRMRP topic area? Is there a clear link between the individual research projects, the theme of the program, the training program (if applicable), and the collaborations? If the program includes multiple approaches such as basic, animal, human subjects, and/or rehabilitation research, are the components well integrated? Is the proposal well written, with all the components of the program including the core facility (if applicable) clearly described (including their integration) and justified?
- **Accomplishments and Productivity:** Have major research findings resulting from the program been described and submitted, including a list of publications and presentations? Has the impact of the program with regard to its stated goals been elucidated? Has the status of each ongoing or concluded project been submitted? Have future plans for the individual projects and the program been clearly described?

d. **<u>Advanced Technology Development Award</u>:** The following review criteria supersede any listed in the current BAA; they serve as the sole peer review criteria for Advanced Technology Development proposals.

- **Research Strategy and Objectives:** Is the proposal well conceived and clearly described? Are the study design, methods, and analyses adequately developed, appropriate, and well integrated to the aims of the project? Has a brief summary of competing products or technologies and the cost/benefit of support for this product/technology been provided? Does the applicant acknowledge potential problem areas and consider alternative methods/techniques? Are the appropriate collaborative agreements needed to support the product/technology development established?
- **Impact:** Does the proposal address an important problem and directly address the selected FY05 PRMRP topic area? What will be the effect of these studies on the concepts or methods that drive this field? What is the likelihood that the resulting

product/technology will be patented and fielded (provided to the end user)? If successful, is the proposed work likely to result in the successful development of an important military health-related product or technology?

- **PI and Key Personnel Qualifications:** Is the PI appropriately trained and well suited to guide this project? **Have the PI and other key personnel committed a sufficient level of effort to ensure the success of this project?** Are appropriate personnel or other sources of expertise available to successfully complete product/technology development to the stage of development proposed within the grant period? Are conflicts-of-interest and commercial interests adequately identified and justified (if applicable)? If the PI has been funded by the CDMRP in the past, has sufficient progress been made in the funded project? If not, are the reasons presented adequately (as described in the PI past performance summary)?
- **Facilities:** Is the scientific environment appropriate for the proposed product/technology development? Is there evidence that the product/technology development requirements are adequately supported by proposed collaborative arrangements (if applicable)? Is there evidence of sufficient administrative support? Is there evidence of adequate institutional support (space and equipment) provided with the proposal?
- **Human Subjects Research Review (if applicable):** Has the PI adequately described the objective as well as the procedure of clinical study? Are the proposed recruitment process, the consent process, and the plan for study subject confidentiality reasonable? Does the PI adequately explain the risk and intent to benefit from findings of the study? When applicable, does the PI provide a status FDA submission(s) (IND, IDE, NDA, PMA, 510K, etc.). Does the PI sufficiently explain what safety monitoring procedures will be used in the protocol?
- **Budget:** Is the budget well justified and appropriate for the technology development proposed? Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultants, equipment costs, subawards, or the scope of the research (time or aims)? Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project? Are other sources of funding adequately described? If there is a need for funding beyond the time period of the grant, have other potential sources of funding (e.g., commercial) to complete the product/technology development been identified? What would the impact on the technology development be without continuation of funding beyond the grant period?
- **Prior Accomplishments:** Has a summary of previous work on this product or technology been provided? Have changes to the initial development plan and rationale for the changes (if applicable) been described? Do the previous results described in this proposal and the current status of the product/technology support the proposed development plans? Have patents been developed or allowed, and have the appropriate details been submitted? If applicable, have regulatory issues been addressed (examples include: addressing FDA requirements for an

investigational new drug or investigational device exemption; use of good manufacturing processes or GCP)?

3. Programmatic Review: The second tier of proposal review, programmatic review, is conducted by a team of federal and military scientists and clinicians. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. Panel members use the peer review summary statements (not the full proposals), Military Relevance Statements, Transition Plans for the Advanced Technology Funding Mechanism, and Federal Agency Financial Plans to make funding recommendations. The SOW may also be reviewed at this level. The ratings and evaluations of peer review panels are primary factors in programmatic review. Programmatic reviewers also use the following 10 criteria to assist in making their recommendations:

- Peer review recommendations
- Relevance of proposed research to military health
- Relevance/alignment to topic area
- Programmatic priorities, which include congressional guidance, DOD priorities, VA priorities, and collaborations with federal researchers
- PRMRP portfolio balance
- Budget
- Transition Plan for the Advanced Technology Development Funding Mechanism
- Federal Agency Financial Plan (projected review criteria if plan is workable)
- Past performance on CDMRP research awards
- Human Subjects Research Review (3 page summary)

Scientifically sound proposals that best fulfill the above peer and programmatic review criteria and most effectively address the unique focus and goals of the PRMRP will be recommended to the Commanding General, USAMRMC, for funding.