**Fiscal Year 2004 (FY04)**
**Department of Defense (DOD)**
**Peer Reviewed Medical Research Program (PRMRP)**
**Supplement to the US Army Medical Research and Materiel Command (USAMRMC)**
**Broad Agency Announcement (BAA) 02-1**

## I. OVERVIEW OF THE FY04 PRMRP

The USAMRMC has been directed to conduct innovative research and development with specific goals and endpoints. The Defense Appropriations Act of 2004 (Public Law 108-87) 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 FY04 PRMRP must be scientifically meritorious and must clearly explain the military relevance of the proposed efforts.

Proposals are being solicited from agencies of local, state, and federal governments; educational institutions; non-profit 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.

**In order to complete submission requirements for the FY04 PRMRP, applicants will need a copy of this FY04 Supplement, the USAMRMC BAA 02-1, and appropriate appendices. The USAMRMC BAA 02-1 is available at http://www.usamraa.army.mil/pages/index.cfm.**

**Once you access the website:**

- **Click on the "BAA" link (located on the left-hand side).**
- **Click on "USAMRMC BAA 02-1" to access the BAA 02-1, Appendices, sample Technical Abstract, and sample Statement of Work.**
- **Click on "USAMRMC BAA Announcements" to access the electronic version of this FY04 Supplement.**

**All guidelines contained in the FY04 Supplement supersede BAA 02-1 instructions. Those sections in BAA 02-1 that must be referenced for proposal preparation are noted in this supplement by page number.**

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 6). Applicants are expected to survey the peer-reviewed literature in order 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 FY04 PRMRP research topic listed on the following page, 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://www.va.gov/resdev
- http://www.acq.osd.mil

## II. GENERAL INFORMATION

**A. Electronic Submission:** All proposals and supporting documentation must be submitted electronically to the FY04 PRMRP. Electronic submission of proposals differs from the USAMRMC BAA 02-1 submissions. **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 section C.

**C. Questions Related to Electronic Submission:** 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: | mailto: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.
- The e-mail address of a Contract Representative from the applicant's Sponsored Programs Office (or equivalent) must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- 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 16, 2004 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 Justifications Form. Budget Information must be uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

- Numerous Regulatory, Compliance, and Quality (RCQ) and US Army Medical Research Acquisitions Activity (USAMRAA) documents are required at submission (see sections IV-G and IV-H of this Supplement). Regulatory documents must be uploaded under the "Required Files" tab and USAMRAA documents must be uploaded under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system.

**F. Cost Sharing:** It is expected that institutions will cost share. Please see full details in subsection IV-F, under **Detailed Cost Estimate and Justifications 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 over 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 note, each award mechanism has specific requirements regarding human subjects and animal use. Please see section IV-G for specific requirements.

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 applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ 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 these topic areas for consideration):

- Amyotrophic Lateral Sclerosis
- Alcoholism Research
- Anti-diarrhea Supplement
- Blood-related Cancer Research
- Childhood Asthma
- Chronic Pain Research
- Epilepsy Research
- Geneware Rapid Vaccine Development
- Interventional Cardiovascular Magnetic Resonance Imaging Technologies
- Muscle Function Research
- Malaria Vaccine Initiative [SBRI]
- Muscular Dystrophy
- Osteoporosis and Bone Related Disease Research
- Padget's (sic) Disease
- Providence Cancer Research Project
- Post-traumatic Stress Disorder
- Social Work Research
- Interstitial Cystitis
- Military Medical Informatics Research
- Limb Loss and Paralysis Research
- Reserve Component Medical Training Program
- Smoking Cessation
- Pseudofolliculitis Barbae
- Lung Cancer Screening
- Military Relevant Disease Management (especially research on Malaria, Leishmaniasis, and Wound Infections)

**Failure to specifically and thoroughly address a given topic area will result in a negative peer and programmatic review evaluation.**

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

1. **Investigator-Initiated:** This traditional award mechanism is intended to support basic or clinical military-relevant research studies focused on a target area solicited in the FY04 Supplement to the BAA 02-1.
2. **New Program Project:** This award mechanism is intended to establish a multidisciplinary program in a target area solicited in the FY04 Supplement to the BAA 02-1.
3. **Existing Program Project:** This award mechanism is intended to support the continuation of a multidisciplinary program in a target area solicited in the FY04 Supplement to the BAA 02-1.
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 the FY04 Supplement to the BAA 02-1.

**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 FY04 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 $2M will be negatively considered. Additionally, no more than 15% (approximately $6.3M) of the FY04 PRMRP budget will be used to fund Program Projects.

| Award Mechanism | Recommended Maximum Budget | Period of Performance |
|---|---|---|
| Investigator-Initiated | $2M | 4 years |
| Program Project (New or Existing) | $2M | 4 years |
| Advanced Technology | $2M | 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 Supplement to the BAA 02-1.

**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. LOI's will be used to aid in determining proposal submission intent.
- **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.
- **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. See section IV-G of this Supplement for the specific documents that are required.

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

- **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, 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 16, 2004. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern Time, March 16, 2004 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 who is authorized to negotiate on behalf of the institution.

- **Letter of Intent:** All applicants considering submission of a proposal in response to this Supplement to the USAMRMC BAA 02-1 are expected to submit an electronic LOI by **February 11, 2004**, but no later than **March 1, 2004**. Your 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 at https://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: 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. A sample SOW is included in the USAMRMC BAA 02-1 (please refer to the instructions on how to access the BAA 02-1 on the first page of this Supplement).

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. As appropriate, the SOW should:

- Describe the work 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
    - Animal or human use at this site

## D. Technical Abstract and Military Relevance Statement:

**1. 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 http://www.usamraa.army.mil/pages/index.cfm. The abstract is vitally 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 upon 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.

**2. 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 topic to the selected topic area. In cases where the proposed study involves military recruits or subjects, military controlled study materials, databases, and/or restricted facilities (i.e., Biological or Chemical Containment Facilities), clearly identify the military collaborations/subawards/study sites and contributions to the study. The appropriate verification letter(s) of support should be uploaded as part of the study (see section IV-E (2), page 10).

## E. 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. 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 top, bottom, right, and 1-inch left
- **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:** 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm)

**2. Sections of the Proposal (Note: These sections should be scanned into one PDF file before uploading): <u>All guidelines contained in the FY04 Supplement supersede BAA 02-1 instructions.</u>**

- **Research Proposal Cover Page:** Use the instructions and form provided in BAA 02-1, Appendix 3, which can be found at http://www.usamraa.army.mil/pages/index.cfm. (See the third paragraph of page 1 of this Supplement for further details).

- **Table of Contents/Checklist:** Prepare a Table of Contents/Checklist, with page numbers, using the form provided on page 18 of this Supplement. 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. Prepare the proposal body using the guidelines provided in BAA 02-1, page 21. **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.**

- **Appendices:** Page limits apply to certain appendices: Use the instructions and forms provided in BAA 02-1 (see pages 24-25 and Appendices 7 and 11). Refer to each section below for specific details. Each section below can be accessed on the Internet at http://www.usamraa.army.mil/pages/index.cfm. (See the third paragraph of page 1 of this Supplement for further details).

- **Acronym and Symbol Definition:** See BAA 02-1, page 24

- **Bibliography:** See BAA 02-1, page 24

- **Table of Contents/Checklist:** See BAA 02-1, page 24 and Appendix 7-1 and 7-2

- **Existing/Pending Support:** See BAA 02-1, page 25

- **Facilities/Equipment Description:** See BAA 02-1, page 25

- **Verification Letters for Access to Military Recruits or Subjects and Materials:** See BAA 02-1, page 25. **All guidelines contained in the FY04 Supplement supersede BAA 02-1 instructions.** In cases where the proposed studies involve military recruits or subjects, military controlled study materials, databases and restricted facilities (i.e. 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. 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 16, 2004**). 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 should be sent to the following address no later than **June 18, 2004**. 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**

**F. Budget Information: <u>All guidelines contained in the FY04 Supplement supersede BAA 02-1 instructions</u>.** Budget Information includes the detailed cost estimate forms, budget justification, 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 16, 2004**. **(Note: Upload a new PDF file for this section).** The budget information will be forwarded to both tiers of review.

- **Detailed Cost Estimate and Justifications Form Instructions:** Use the Detailed Cost Estimate instructions provided in BAA 02-1, pages 21-24 and the forms provided in Appendix 6 (located at http://www.usamraa.army.mil/pages/index.cfm) 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. **Additionally,** it is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated. Moreover, 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 $2500.

- **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 16, 2004**. Proposals from federal agencies are **expected to** provide a plan delineating how all funds will be obligated by September 30, 2004, 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: Financial Plan requirements are not included in the BAA 02-1.)

**Note: The maximum budget is inclusive of direct and indirect costs. Budgets greater than $2M will be negatively considered.**

**G. 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 16, 2004** receipt deadline.

1. **Certification of Environmental Compliance:** This form can be found at https://cdmrp.org/programAnnouncements.cfm.

2. **Safety Program Documents:** See BAA 02-1, page 25 and Appendix 11 (found at http://www.usamraa.army.mil/pages/index.cfm).

3. **Research Involving Animals:** See BAA 02-1, page 25 and Appendix 10 (found at http://www.usamraa.army.mil/pages/index.cfm).

4. **Research Involving Human Subjects and/or Anatomical Substances:** See BAA 02-1, page 25 and Appendix 9 (found at http://www.usamraa.army.mil/pages/index.cfm). **The DOD considers cell lines of human origin to be human anatomical substances.**

**H. 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 16, 2004** 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.

**I. 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 BAA 02-1, which can be submitted throughout the year, **FY04 PRMRP proposals must be submitted electronically by 5:00 p.m. Eastern Time, on March 16, 2004, 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 FY04 PRMRP is:**

| | |
|---|---|
| Online Letter of Intent: | Expected by **February 11, 2004** |
| Online Proposal Information: | **Prior to proposal submission** |
| **Proposal Submission/Approval Deadline:** | **5:00 p.m. Eastern Time, March 16, 2004** |
| RCQ and USAMRAA Documents: | **5:00 p.m. Eastern Time, March 16, 2004** |
| Peer Review: | **May 2004** |
| Programmatic Review: | **July 2004** |
| 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 2004 and September 2005** |

## V. PROPOSAL REVIEW INFORMATION

### A. Proposal Review and Selection Overview

1. **Process:** The CDMRP uses a two-tiered 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 FY04 PRMRP and supersede any evaluation criteria that are listed in the BAA 02-1.**

**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 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, 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 Awards:</u>** The following review criteria supersede any listed in the BAA 02-1; they serve as the sole peer review criteria for Investigator-Initiated 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 FY04 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)?

- **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?

- **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 BAA 02-1; 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 FY04 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)? 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?

- **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 cost share?

- **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 FY04 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.** **Existing Program Project Awards:** The following review criteria supersede any listed in the BAA 02-1; 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 FY04 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)? 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?

- **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 cost share?

- **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 FY04 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 BAA 02-1; 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 FY04 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)?

- **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?

- **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, consultant, 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 Food and Drug Administration requirements for an investigational new drug or investigational device exemption; use of good manufacturing processes or good clinical practices)?

**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 nine 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
- Past performance on DOD Research awards to include time of initiation of research
- Transition Plan for the Advanced Technology Development Funding Mechanism (refer to page 10 of this supplement)
- Federal Agency Financial Plan (projected review criteria if plan is workable) (refer to page 11 of this supplement)

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.

**Fiscal Year 2004 Peer Reviewed Medical Research Program**
**Table of Contents/Checklist**

**Proposal Log Number:** _____

**Principal Investigator:** _____
*Last Name* *First Name* *MI*

**Proposal Topic Area[1]:** _____

**Proposal Title:** _____

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**Award Mechanism (Select only <u>one</u> of the following mechanisms):**
□ Investigator-Initiated Research □ New Program Project
□ Advanced Technology Development □ Existing Program Project



NOTE: Exceeding page limits may result in proposal rejection prior to peer review. Submit only materials specifically requested or required in this Supplement to the Broad Agency Announcement. Submission of additional materials may be construed as an attempt to gain an unfair advantage.

[1] Select one topic area from the list on page 5 of this Supplement.