

Fiscal Year 2003 (FY03)
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 FY03 PRMRP

The USAMRMC has been directed to conduct innovative research and development with specific goals and endpoints. The Defense Appropriations Act of 2003 (Public Law 107-248) 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 FY03 PRMRP must be scientifically meritorious and address 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. Applicants are encouraged to collaborate with federal agencies (military treatment facilities and research laboratories, the Department of Veterans Affairs, the Centers for Disease Control and Prevention, etc.).

In order to complete submission requirements for the FY03 PRMRP, applicants will need a copy of this FY03 Supplement and the USAMRMC BAA 02-1, which is available at <http://www.usamraa.army.mil/pages/index.cfm>. Once you access the web site, click on the "BAA" link (located on the right-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 FY03 Supplement. All guidelines contained in the FY03 Supplement supercede 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 5). 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 web site at <http://www.dtic.mil>. To help identify DOD specific areas of interest within each FY03 PRMRP research topic listed on the following page, applicants are encouraged to review ongoing research described on the following web sites:

- <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. AWARD INFORMATION

A. 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 FY03 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 FY03 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 FY03 Supplement to the BAA 02-1.
- 4. Advanced Technology:** 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 FY03 Supplement to the BAA 02-1.

B. General Budget Guidelines: Budget requests are a component of the peer and programmatic review evaluation process. Budget guidelines and award lengths for each award mechanism offered by the FY03 PRMRP are shown in the following table.

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

¹Inclusive of direct and indirect costs.

²No more than 15% (approximately \$6.3M) of the FY03 PRMRP budget will be used to fund Program Projects.

C. Research Topic Areas (Note: Your proposal must fit within one of these topic areas for consideration):

- Acellular Matrix Research for Military Orthopedic Trauma
- Alcoholism Research
- Amyotrophic Lateral Sclerosis
- Anti-Diarrhea Supplement
- Army Nutrition Research
- Augmented Care in the Chain of Stroke Survival (ACCESS)
- Blood-Related Cancer Research
- Bone-Related Disease Research
- Cell Response to Anti-Cancer Agents
- Mt. Sinai Cancer Research Program
- Casualty Care Research Center
- Chiropractic Care
- Epilepsy
- Infectious Disease Tracking System
- Interstitial Cystitis Research
- Low Vision Research
- Medical Digital Assistance
- Military-Relevant Disease and Injury
- Miniature Renal Assist Devices
- Natural Toxin Detection Technology
- Neuroscience Research
- Paget's Disease
- Personal Intelligent Medical Assistant
- Providence Cancer Center
- Respiratory Research
- Smoking Cessation
- Social Work Research
- Volume Angio CAT (VAC) Research

III. GENERAL INFORMATION

A. Electronic Submission: All proposals and supporting documentation must be submitted electronically to the FY03 PRMRP. Electronic submission of proposals differs from former PRMRP and USAMRMC BAA 02-1 submissions. **No paper copies will be accepted.**

B. Web Site to Access Application Package: Proposals must be submitted electronically at <http://cdmrp.org/proposals>. This web site 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. The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Web Site: <http://cdmrp.org/proposals> (the proposal submission web site)
E-mail: help-proposals-cdmrp@cdmrp.org

D. For Non-eReceipt-Related Questions, 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 must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the applicant's Sponsored Programs Office who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- **If final approval is not accomplished by the submission deadline, the proposal will be considered a "LATE" submission and will not be considered for review.**
- 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 under the “File Upload” 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-H and IV-I of this Supplement). RCQ and USAMRAA documents must be uploaded under the “File Upload” tab of the CDMRP eReceipt system.

F. 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.

Failure to comply with any of the five items listed below 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 submitted 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 CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

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.
- **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 “File Upload” tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the “File Upload” tab.
- **RCQ Documents:** These documents are each uploaded as separate PDF files under the “File Upload” tab. See section IV-H 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 must provide approval of all proposal components (Proposal Information, SOW, Structured Technical Abstract, Military Relevance Statement, Proposal, Budget Information, and RCQ documents). Contract Representative approval must occur prior to the submission deadline of **5:00 p.m. (Eastern Time) April 17, 2003**. Otherwise, the entire proposal will be considered a “LATE” submission and will not be forwarded for review.

B. Proposal Information (Previously Called the Proposal Cover Booklet): Applicants are required to submit the Proposal Information, Parts 1 and 2 (referred to in previous years as Proposal Cover Booklet), prior to upload of the proposal and the budget information. Complete the Proposal Information as described at <http://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.

C. LOI: 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 28, 2003**, but no later than **April 3, 2003**. 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 <http://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).

D. 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) projected or required for each task
- Identify methods
- Identify products/deliverables for each phase of the project
- 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

E. 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 based upon the Joint Programmatic Review Panel'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 web site 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.

F. Proposal

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the “File Upload” 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, but applicants should keep in mind that 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):

- **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:** This document can be found on page 17 of this Supplement.
- **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.
- **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.**
- **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
- **Biographical Sketch:** 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
- **Collaboration and Joint Sponsorship:** See BAA 02-1, page 25. In addition, in cases where the proposed studies involve military recruits or subjects, a letter of support signed by the Installation Commander(s) and appropriate Troop

Commander(s) confirming access to recruits/military subjects is required. Preferably, this letter of support should be uploaded electronically at this location at the time of proposal submission (no later than **5:00 p.m. Eastern Time, April 17, 2003**). If the letter 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 **July 28, 2003**. 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

G. Budget Information: Budget Information includes the detailed cost estimate forms and budget justification. Budget Information must be uploaded under the “File Upload” tab of the CDMRP eReceipt system prior to the receipt deadline of **5:00 p.m. (Eastern Time) April 17, 2003**. (Note: Upload a new PDF file for this section)

Detailed Cost Estimate and Justifications Form Instructions: 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. 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>).

NOTE: Proposals from federal agencies should provide a plan delineating how expenditures will be obligated over the course of the grant. The plan should include mechanisms used to ensure carry over of funds between years such as administrative agreements with nonfederal institutions, foundations, and universities.

H. RCQ Requirements: Completed and signed copies of each of the documents listed below must be uploaded as separate PDF files using the “File Upload” tab of the CDMRP eReceipt system by the **April 17, 2003** receipt deadline.

- 1. Certification of Environmental Compliance:** This form can be found at <http://cdmrp.army.mil/funding/pdf/cec.pdf>.
- 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>).

I. USAMRAA Requirements: A copy of the documents listed below must be uploaded by the Contract Representative from the applicant's Sponsored Programs Office. These documents must be uploaded as separate PDF files using the Contract Representative "My Profile" tab of the CDMRP eReceipt system by the **April 17, 2003** 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 <http://cdmrp.army.mil/funding/pdf/certs.pdf>.
- 3. Representations for Assistance Agreements:** This form can be found at <http://cdmrp.army.mil/funding/pdf/certs.pdf>.

J. Submission 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, **FY03 PRMRP proposals must be submitted electronically by 5:00 p.m. (Eastern Time) on April 17, 2003, or they will not be considered for review.**

The general timeline for the FY03 PRMRP is:

Online Letter of Intent:	Recommended by February 28, 2003 but no later than April 3, 2003
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time April 17, 2003
RCQ and USAMRAA Documents:	5:00 p.m. Eastern time April 17, 2003
Peer Review:	June 2003
Programmatic Review:	August 2003
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 2003 and September 2004

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 as well as overall program goals. **The proposal evaluation criteria listed below are specific to the FY03 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 upon 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 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. **Investigator-Initiated Awards:** The following review criteria supercede 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 FY03 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? 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 supercede 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 FY03 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? 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, do they 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 FY03 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 supercede 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 FY03 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? 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, do they 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 FY03 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 value of the program as it relates to the mission of the DOD been shown? 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. **Advanced Technology Development Award:** The following review criteria supercede 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 FY03 PRMRP topic area? What will be the effect of these studies on the concepts or methods that drive this field? Has the value of the product/technology as it relates to the mission of the DOD been shown? 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 researchers. 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) to make funding recommendations. The SOW may also be reviewed at this level. The ratings and evaluations of scientific peer review panels are primary factors in programmatic review.

Programmatic reviewers also use the following four criteria to assist in making their recommendations:

- Peer review recommendations
- Relevance of proposed research to military health
- Programmatic priorities, which include congressional guidance, DOD priorities, Veterans Affairs priorities, and collaborations with federal researchers
- PRMRP portfolio balance

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 2003 Peer Reviewed Medical Research Program Table of Contents/Checklist

Proposal Log Number: _____

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

Proposal Topic Area¹: _____

Proposal Title: _____

Award Mechanism (Select no more than one of the following mechanisms):

- | | |
|----------------------------------------------------------|---------------------------------------------------|
| <input type="checkbox"/> Investigator-Initiated Research | <input type="checkbox"/> New Program Project |
| <input type="checkbox"/> Advanced Technology Development | <input type="checkbox"/> Existing Program Project |

Yes	Page Number
<input type="checkbox"/> Proposal Information	N/A
Letter of Intent (requested by February 28, 2003)	N/A
<input type="checkbox"/> Statement of Work (11,400 character limit)	N/A
<input type="checkbox"/> Structured Technical Abstract (5,700 character limit).....	N/A
<input type="checkbox"/> Military Relevance Statement (5,700 character limit).....	N/A
<input type="checkbox"/> Research Proposal Cover Page (1-page).....	1
<input type="checkbox"/> Table of Contents/Checklist (1-page)	2
<input type="checkbox"/> Proposal Relevance Statement (1-page limit)	3
<input type="checkbox"/> Main Body of Proposal (25-page limit)	___
<input type="checkbox"/> Acronym and Symbol Definition (1-page limit)	___
<input type="checkbox"/> Bibliography (no page limit)	___
<input type="checkbox"/> Biographical Sketches (3-page limit per individual)	___
<input type="checkbox"/> Existing/Pending Support (no page limit)	___
<input type="checkbox"/> Facilities/Equipment Description (no page limit)	___
<input type="checkbox"/> Questionnaires, Surveys, or Clinical Protocols (no page limit) – if applicable	___
<input type="checkbox"/> Publications and/or Patent Abstracts (5-document limit) – if applicable.....	___
<input type="checkbox"/> Collaboration and Joint Sponsorship	___
<input type="checkbox"/> Letter of Support Confirming Access to Recruits/Military Subjects – if applicable	___
Submitted with the Proposal	___
To Be Submitted by July 28, 2003	___
<input type="checkbox"/> Budget Information	N/A
Detailed Cost Estimate (no page limit).....	N/A
Budget Justification (no page limit).....	N/A
<input type="checkbox"/> Regulatory Compliance and Quality Documents	N/A
<input type="checkbox"/> US Army Medical Research Acquisition Activity Documents.....	N/A

NOTE: Exceeding page limits may result in proposal rejection prior to peer review. Submit only materials specifically requested or required in this 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 2 of this Supplement.