Fiscal Year 2006 (FY06)
Department of Defense (DOD)
Peer Reviewed Medical Research Program (PRMRP)
Supplement to the U.S. Army Medical Research and Materiel Command (USAMRMC)
Broad Agency Announcement (BAA) 05-1

All guidelines contained in this FY06 Supplement supersede BAA 05-1 instructions.

I. OVERVIEW OF THE FY06 PRMRP

The USAMRMC has been directed to conduct innovative research and development with specific goals and endpoints. The Defense Appropriations Act of 2006 (Public Law 109-359) 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 FY06 PRMRP must be scientifically meritorious and must clearly explain the military relevance of the proposed efforts.

Proposals will be assessed based on how they complement existing DOD research. The submission of a Letter of Intent (LOI) is required to facilitate this objective (see Subsection V.D). Applicants are expected to survey the peer-reviewed literature to avoid duplication of previously described research efforts, including those previously supported by the DOD and/or its investigators. An additional source containing documentation of previously accomplished research supported by the DOD can be found at the Defense Technical Information Center website at http://www.dtic.mil. To help identify DOD-specific areas of interest within each FY06 PRMRP research topic area listed on page 3, applicants are encouraged to review ongoing research described on the following websites:

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

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

II. GENERAL INFORMATION

A. Electronic Submission: All proposals and supporting documentation must be submitted electronically to the FY06 PRMRP. Proposals must be submitted on the site listed below. Proposals and LOIs submitted to any other USAMRMC website will not be accepted. ***No paper copies will be accepted.***

B. Website to Access Application Package: Proposals must be submitted at https://cdmrp.org. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty in downloading documents should contact the CDMRP as indicated in Subsection II.C.

C. Questions Related to Electronic Submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by e-mail as follows:

Website: https://cdmrp.org (User's Guide located in upper right corner of the proposal submission website)
E-mail: help@cdmrp.org

D. Questions Unrelated to CDMRP eReceipt: For non-eReceipt-related questions (for example, questions regarding certifications and assurances for Assistance Agreements), please contact Ms. Pamela Fisher as follows:

Mail: Ms. Pamela Fisher
USAMRAA
MCMR-AAA-R
820 Chandler Street
Fort Detrick, MD 21702-5014
Phone: 301-619-2805
Email: Pam.Fisher@amedd.army.mil

E. Anticipated Instrument Type(s): The USAMRMC executes its extramural research program predominantly through the award of grants, cooperative agreements, and/or contracts. More information on these funding instruments may be obtained by request from:

Fax: 301-619-2937
E-mail: qa.baa@amedd.army.mil
Mail: Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-R
820 Chandler Street
Fort Detrick, MD 21702-5014

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

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human biological substances, or laboratory animals without express written permission from the USAMRMC Office of Research Protection. The USAMRMC Office of Research Protection 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: ***Your proposal must specifically and clearly address one of the topic areas listed below. Failure to specifically and thoroughly address a given topic area will result in a negative peer and programmatic review evaluation. (Note: The Government reserves the right to reassign the proposal's topic area if submitted under an inappropriate topic area. If the research has no relevance to currently advertised PRMRP topic areas, the Government reserves the right to disqualify the proposal.)***

- Advanced Proteomics
- Alcoholism Research
- Autism
- Autoimmune Diseases such as Scleroderma and Sjogren's Syndrome
- Blood-Related Cancer Research such as Leukemia, Lymphoma, and Multiple Myeloma
- Childhood Asthma
- Chronic Pain and Fatigue Research
- Childhood Cancer Research
- Diabetes Research
- Duchenne's Disease Research
- Eye and Vision Research
- Fibromyalgia
- Interstitial Cystitis Syndrome
- Kidney Cancer Research
- Lupus Research
- Military Relevant Disease Management[1] with special emphasis on:
  - Antibiotic Resistance;
  - Neurotoxicity of Mefloquine;
  - Rehabilitation (Face and/or Eye Injury);
  - Respiratory Infection Including Associated Respiratory Disease;
  - Drug Abuse;
  - Efficacy and Subsequent Clinical Guidelines for the Use of Probenecid or Other Drugs to Decrease Dosage Requirements of Oseltamivir Phosphate for the Treatment of Influenza;
  - Human Performance Optimization;
  - Radio-Protectants; and
  - Mental Health Resiliency
- Osteoporosis and Bone-Related Diseases
- Polycystic Kidney Disease
- Pulmonary Hypertension
- Paget's Disease
- Post traumatic Stress Disorders
- Social Work Research

[1] Topic Area added by Health Affairs

B. Award Mechanisms: In this FY06 Supplement to the BAA 05-1, the PRMRP is offering five award mechanisms: the Investigator-Initiated Research Award; New Program Project Award, Existing Program Project Award, Advanced Technology: Product/Technology Down-Selection or Optimization Award; and Advanced Technology: Clinical Testing/Trials (Human Subjects) Award. ***You must select only one of the mechanisms described below for your submission*:**

1. **Investigator-Initiated Research Award**

   a. Award Mechanism Description: The intent of the PRMRP Investigator-Initiated Research Award is to encourage basic or clinical military-relevant health research in response to one of the topic areas solicited in this FY06 Supplement to the USAMRMC BAA 05-1. The PRMRP seeks proposals from all agencies of local, state, and Federal governments; educational institutions; nonprofit organizations; and private industry. Important aspects of the Investigator-Initiated Research Award are as follows:

   i. Military Relevance: Military relevance is a key feature of the Investigator-Initiated Research Award. Military-relevant research (basic and clinical) must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. To this end, applicants are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs.

   ii. Responsiveness to FY06 PRMRP Topic Area: Projects must address a military-relevant health problem responsive to one of the FY06 PRMRP topic areas.

   iii. Access to Target Military Population(s) (if applicable): It is critical that applicants proposing to study military populations provide confirmation of approval for access from appropriate troop authority.

   iv. Animal, Human Anatomical and Biological Substances, and Human Use Regulatory Approvals: The applicant must make a strong case for the study's potential for Institutional Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB) approval.

   v. Anticipated Outcomes: Outcomes may significantly advance current concepts and/or methods that drive the target military-relevant field of knowledge. To that end, data relevant to the development of a military-relevant product or technology may be generated.

2. New Program Project Award

a. Award Mechanism Description: The intent of the PRMRP New Program Project Award is intended to establish a multidisciplinary program focused on a specific and important military-relevant medical condition, injury, or disease process related to the selected FY06 PRMRP topic areas solicited in this FY06 Supplement to the BAA 05-1. The PRMRP seeks proposals from all agencies of local, state, and Federal governments; educational institutions; nonprofit organizations; and private industry. Important aspects of the New Program Project Award are as follows:

i. Military Relevance: Military relevance is a key feature of the New Program Project Award. Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. To this end, applicants are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs.

ii. Responsiveness to FY06 PRMRP Topic Area: Projects must address a military-relevant health problem responsive to one of the FY06 PRMRP topic areas.

iii. Access to Target Military Population(s) (if applicable): It is critical that applicants proposing to study military populations provide confirmation of approval for access from appropriate troop authority.

iv. Advisory Committee: A committee of external advisors may be used for studies proposed under this mechanism. The proposal should identify committee members and define the role of the committee along with the proposed means and schedule of correspondence and/or meetings. The proposal also should include letters of support from committee members.

v. Animal, Human Anatomical and Biological Substances, and Human Use Regulatory Approvals: The applicant must make a strong case for study's potential for IACUC and/or IRB approval.

vi. Anticipated Outcomes: New Program Projects are expected to establish a strong multidisciplinary (collaborative) research project aimed at elucidating an important military-relevant health issue responsive to a topic area solicited in the FY06 PRMRP Supplement to the USAMRMC BAA 05-1.

3. Existing Program Project Award

a. Award Mechanism Description: The intent of the PRMRP Existing Program Project Award is to support the continuation of a multidisciplinary program focused on a specific and important military-relevant medical condition, injury, or disease process related to the selected FY06 PRMRP topic area solicited in this FY06 Supplement to the BAA 05-1. The PRMRP seeks proposals from all agencies of local, state, and Federal

governments; educational institutions; nonprofit organizations; and private industry. Important aspects of the Existing Program Project Award are as follows:

i. Military Relevance: Military relevance is a key feature of the Existing Program Project Award. Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. To this end, applicants are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs.

ii. Responsiveness to FY06 PRMRP Topic Area: Projects must address a military-relevant health problem responsive to one of the FY06 PRMRP topic areas.

iii. Access to Target Military Population(s) (if applicable): It is critical that applicants proposing to study military populations provide confirmation of approval for access from appropriate troop authority.

iv. Advisory Committee: A committee of external advisors may be used for studies proposed under this mechanism. The proposal should identify committee members and define the role of the committee along with the proposed means and schedule of correspondence and/or meetings. The proposal also should include letters of support from committee members.

v. Animal, Human Anatomical and Biological Substances, and Human Use Regulatory Approvals: The applicant must make a strong case for the study's potential for IACUC and/or IRB approval.

vi. Existing Program Project Status: Details on all ongoing projects (to include findings and outcomes) and plans for extended research and new projects must be clearly articulated.

vii. Anticipated Outcomes: Existing Program Projects are expected to build upon the research findings and strategy related to the ongoing multidisciplinary (collaborative) military-relevant research project.

4. Advanced Technology: Product/Technology Down-Selection or Optimization Award

a. Award Mechanism Description: The intent of the PRMRP Advanced Technology: Product/Technology Down-Selection or Optimization Award is to assess product or technology scientific and business feasibility and to determine product or technology readiness to move into clinical studies. The PRMRP seeks proposals from all agencies of local, state, and Federal governments; educational institutions; nonprofit organizations; and private industry. Important aspects of the Advanced Technology: Product/Technology Down-Selection or Optimization Award are as follows:

i. Military Relevance: Military relevance is a key feature of the Advanced Technology: Product/Technology Down-Selection or Optimization Award. Military-relevant research (in vitro, animal and/or human biological substances) must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. To this end, applicants are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs.

ii. Responsiveness to FY06 PRMRP Topic Area: Projects must address a military-relevant health problem responsive to one of the FY06 PRMRP topic areas.

iii. Access to Target Military Population(s) (if applicable): It is critical that applicants proposing to study military populations provide confirmation of approval for access from appropriate troop authority.

iv. Animal and Human Anatomical and Biological Substances Regulatory Approvals: The applicant must make a strong case for the study's potential for IACUC and/or IRB approval.

v. Advisory Committee: A committee of external advisors may be used for studies proposed under this mechanism. The proposal should identify committee members and define the role of the committee along with the proposed means and schedule of correspondence and/or meetings. The proposal also should include letters of support from committee members.

vi. Product or Technology Transition: A plan for further product or technology development and/or transition to advanced development (including potential funding and resources) is required.

vii. Anticipated Outcomes: Advanced Technology: Product/Technology Down-Selection or Optimization Awards are expected to yield potential military-relevant health products or technologies positioned for human testing. Appropriate U.S. Food and Drug Administration (FDA) meetings, applications, and approvals are also expected.

5. Advanced Technology: Clinical Testing/Trials (Human Subjects) Award

a. Award Mechanism Description: The intent of the PRMRP Advanced Technology: Clinical Testing/Trials (Human Subjects) Award is to assess product/technology scientific and business feasibility and to determine readiness to transition product to an advanced developer**.** The PRMRP seeks proposals from all agencies of local, state, and Federal governments; educational institutions; nonprofit organizations; and private industry. Important aspects of the Advanced Technology: Clinical Testing/Trials (Human Subjects) Award are as follows:

i. Military Relevance: Military relevance is a key feature of the Advanced Technology: Clinical Testing/Trials (Human Subjects) Award. Military-relevant research (human subject-focused) must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. To this end, applicants are strongly encouraged to collaborate and integrate their projects with military and/or VA research laboratories and programs.

ii. Responsiveness to FY06 PRMRP Topic Area: Projects must address a military-relevant health problem responsive to one of the FY06 PRMRP topic areas.

iii. Access to Target Military Population(s) (if applicable): It is critical that applicants proposing to study military populations provide confirmation of approval for access from appropriate troop authority.

iv. Advisory Committee: A committee of external advisors may be used for studies proposed under this mechanism. The proposal should identify committee members and define the role of the committee along with the proposed means and schedule of correspondence and/or meetings. The proposal also should include letters of support from committee members.

v. Product or Technology Transition: A plan for further product or technology development and/or transition to advanced development (including potential funding and resources) is required.

vi. Human Use Regulatory Approvals: The applicant must make a strong case for the study's potential for IRB approval.

vii. Anticipated Outcomes: Advanced Technology: Clinical Testing/Trials (Human Subjects) Awards are expected to yield military-relevant health products or technologies positioned for advanced development. Appropriate FDA meetings, applications, and approvals also are expected.

C. General Budget Guidelines: Budget requests are an important component of the peer and programmatic review evaluation processes. The maximum direct costs can be requested over the performance period. The performance period can be requested for up to 4 years. Indirect costs should be added as appropriate.

Failure to adhere to the budget guidelines listed below may result in proposal rejection.

Award Mechanism	Direct Costs (Maximum)	Performance Period (Maximum)
Investigator-Initiated Research	$625,000	4 years
New Program Project	$1.25M	4 years

Award Mechanism	Direct Costs (Maximum)	Performance Period (Maximum)
Existing Program Project	$1.25M	4 years
Advanced Technology: Product/Technology Down-Selection or Optimization	$940,000	4 years
Advanced Technology: Clinical Testing/Trials (Human Subjects)	$2.5M	4 years

D. PRMRP Funding History: Listed below are the number of submissions and the number of awards made since the inception of the PRMRP. The PRMRP expects to fund the number of anticipated awards listed below, depending on the quality and number of proposals received.

Award Mechanism	Number of Submissions	Number of Awards Funded	Number of Anticipated Awards
Investigator-Initiated Research	1297[a]	86	33
New Program Project	68[b]	5	2
Existing Program Project	6[b]	1	2
Advanced Technology: Product/Technology Down-Selection or Optimization	Not Previously Offered	Not Applicable	3
Advanced Technology: Clinical Testing/Trials (Human Subjects)	Not Previously Offered	Not Applicable	2

[a]Number from FY99-FY05
[b]Number from FY02-FY05

IV. ELIGIBILITY INFORMATION

A. Applicants: Investigators at all academic levels (or equivalent) are eligible to submit proposals.

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined in Subsection IV.B, "Institutions" below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110.)

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

C. Duplicate Submissions: Submission of the same research project to the FY06 PRMRP to different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

V. 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 BAA Supplement. Proposals will be evaluated according to peer and programmatic review criteria in Section VI.

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at https://cdmrp.org:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	Copy the LOI into the data field. Click the "Save and Forward Letter of Intent" button to automatically create the LOI.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative at the applicant's institution.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.

Item	Tab	Format	Action
Proposal Abstracts, Military Relevance Statement (Impact Statement), and Statement of Work (SOW)	Abstract/Impact/ SOW	Typed or Cut and Paste	Enter the Technical Abstract, Public Abstract, and Military Relevance Statement (Impact Statement tab), and SOW in separate data fields.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative Responsibility: The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant's institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative's Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA[a]-Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files ***before*** the submission deadline of 5:00 p.m. Eastern time, May 9, 2006.

[a]US Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission system at https://cdmrp.org. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the

appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05cm x 25.40 cm).
- **Color, High-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 MB. Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- **Language:** English.

Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

C. 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. ***Failure to adhere 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.***

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, pages exceeding the specified limit will be removed from the proposal and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and prior to electronic submission, it is strongly recommended that applicants review their files to ensure that the proposal complies with the preparation guidelines outlined in this BAA Supplement.

D. Letter of Intent (LOI): An LOI (a brief description of the proposal) is entered in a data field under "My Proposals: Create New Proposal." The LOI is saved when the "Save and Forward Letter of Intent" button is chosen. The LOI may be modified under "Proposal Information" at anytime before the applicant submits this information by clicking "Finalize for CR Approval." The LOI should be submitted by ***April 10, 2006*** at https://cdmrp.org.

E. Proposal Information: Applicants are required to submit the Proposal Information as described in https://cdmrp.org before uploading the proposal, supporting documentation, and budget information.

- A ***Title/Referral Page*** for the proposal will be generated from the information uploaded in eReceipt and appended to the proposal electronically by the CDMRP eReceipt system.

F. Proposal Contacts: The Proposal Contacts ***must*** include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant's institution. The Proposal Contacts must be approved by the Contract Representative at the applicant's institution.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators, consultants, and subawardees. In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.

H. Proposal Abstracts: 5,700-character limit including spaces (approximately one page, for each abstract): Abstracts are important to both the peer and programmatic review process. Programmatic review is conducted by the Joint Programmatic Review Panel (JPRP) that is composed of a team of federal and military scientists and clinicians. The programmatic review process is based on the JPRP's evaluation of the abstracts as part of the peer review summary statement; therefore, it is paramount that the investigator submits abstracts that fully describe the proposed work.

Abstracts must contain the title of the proposal and the name of the applicant. The abstracts must be submitted as a data field under the "Abstract/Impact/SOW" tab of the CDMRP eReceipt system. Applicants may type the abstracts or "cut and paste" them from a word processing application into the respective data fields. ***Spell out all Greek letters, other non-English letters, and symbols.***

Abstracts of all funded proposals will be posted on the CDMRP website at https://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included in the technical abstract.

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract must provide a clear and concise overview of the proposed work. Use the outline below when preparing the structured technical abstract.

- Background: Present 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 the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- 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. Public Abstract: A public abstract sample can be found at https://cdmrp.org/Program_Announcements_and_Forms/index.cfm?prg=PRMRP&prg_fy=2006. The public abstract is intended to communicate the purpose and rationale of the study to several audiences.

- Describe the scientific objective and rationale for the proposal in a manner readily understood by various audiences.
  - ***Do not duplicate the technical abstract.***
- Describe how the proposed research will further the relevant field of knowledge or technology area.
- Describe the tasks that will be undertaken during the performance period.
  - ***Do not duplicate the SOW.***
- Describe anticipated outcomes.
- Describe the ultimate applicability of the research.
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a military health-related outcome?

I. Military Relevance Statement: 5,700-character limit, including spaces (approximately one page): The Military Relevance Statement is submitted under the Impact Statement data field within the "Abstract/Impact/SOW" tab of the CDMRP eReceipt system. Applicants may type the Military Relevance Statement into the data field or "cut and paste" it from a word processing application. This statement should describe the military relevance of the proposal and how the proposed research will benefit the military if successful. In cases where the proposed study involves military recruits or subjects, military-controlled study materials, databases, and/or restricted facilities (e.g., biological or chemical containment facilities), the military collaborations/subawards/study sites and contributions to the study should be clearly identified. Note the appropriate verification letter(s) of access to military troops or subjects and materials can be uploaded as part of the proposal if applicable (see Subsection V.L.10).

J. Statement of Work: 11,400-character limit including spaces (approximately two pages): The SOW is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type in the SOW into the data field or "cut and paste" it from a word processing application.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include DOD-funded tasks only.

The SOW should:

- Describe the work (deliverables) to be accomplished as tasks (tasks may relate to specific aims/objectives that are stated in the proposal);
- Identify the timeline (indicated by month(s) or year) and milestones for the work over the period of the proposed effort;
    - Allow 4 to 6 months for regulatory review and approval processes for human use studies;
    - Allow 2 months for regulatory review and approval processes for animal studies;
- Indicate the number of research subjects (animal or human) and/or biological 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-applicant name, and

- Animal or human use at this site.

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

K. Proposal

1. Main Body of Proposal: Start section on a new page; 25-page limit, inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. The following general outline should be followed when preparing the proposal:

a. Background: Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

b. Hypothesis: State the hypothesis to be tested and the expected results.

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

d. Project Milestones: Identify timelines for critical events that must be accomplished for the project to be successful in terms of cost, schedule, and performance.

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

f. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.

L. Supporting Documentation: Submit only material specifically requested in this BAA Supplement. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.*** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting Documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. All documents or letters that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The first item in the Supporting Documentation file is the ***Checklist/Table of Contents page***. The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

1. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.

2. References: Start section on a new page; no page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

3. Biographical Sketches: Four-page limit per individual. Include biographical sketches for all key personnel including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower proposal scores. The Biographical Sketch form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

4. Existing/Pending Support: Start section on a new page; no page limit. List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel on a separate page. If no support exists, enter "None." Proposals submitted under this BAA Supplement should not duplicate other funded research projects.

5. Facilities/Equipment Description: No page limit. Describe the facilities available for performing the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate whether Government-owned facilities or equipment are proposed for use.

6. Letters of Support: Provide letters of support from any collaborating individuals or institutions.

7. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. A maximum of five publication reprints and/or patent abstracts is allowed; extra items will not be peer reviewed.

8. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit. If available at the time of submission, questionnaires, survey instruments, or clinical protocols should be appended. Additionally, append an appropriately titled page listing the documents you have included in this section.

9. Proposal Relevance Statement: One-page limit. Start the Proposal Relevance Statement on a new page. Applicants should state explicitly the proposal's relevance to the selected topic area and its impact on health outcomes. Do not address military relevance in this section; address military relevance as described in Subsection V.I.

10. Verification Letters for Access to Military Recruits or Subjects and Materials: In cases where the proposed studies involve military recruits or subjects, military-controlled study materials, databases, and restricted facilities (e.g., biological or chemical containment facilities), a letter of support signed by the responsible commander (Installation, Troop, or Institute Commander) confirming access to recruits/military subjects and military materials is required. Additionally, a military collaborator is recommended for research involving military troops. These letters of support should be uploaded as part of the proposal at the time of proposal submission (no later than ***5:00 p.m. Eastern time May 9, 2006***). If letters cannot be submitted with the proposal, an electronic copy (in a format readable by IBM-compatible versions of Microsoft Office or Adobe Acrobat) on a formatted disk must be postmarked to the address listed below by ***August 25, 2006***. Failure to submit such a letter (if applicable) will result in proposal rejection at programmatic review.

U.S. Army Medical Research and Materiel Command
MCMR-ZB-C
ATTN: Dr. Barbara Terry-Koroma
1077 Patchel Street
Fort Detrick, MD 21702-5024

11. Applicant Past Performance on CDMRP Awards: One-page limit. Applicants previously funded by the CDMRP are required to provide the following information:

- Title of proposal
- Proposal log number
- Year funded
- Source of CDMRP funding
- Current state of the research, to include additional funding (if applicable)
- Compliance with SOW timeline (if noncompliant, explain rationale for delay(s))
- Significant outcomes, including:
  - Publication of findings
  - Presentations
  - Patents

Please note that the requirements for this summary are different from what is expected under existing/pending support information in that this Applicant Past Performance document applies only to CDMRP awards. Also, the Program Office will be providing past performance data gleaned from past annual reports to the JPRP during programmatic review.

12. Animal Research Review Summary: Three-page limit. When the proposed study involves animals, the applicant is ***required*** to submit a summary describing the animal subject research that will be conducted. The following points must be addressed:

- **Objective of Research**
  - Briefly describe the purpose/research objective of the animal study.
- **Rationale for Using Animals, to include:**
  - Species identification
  - Number of animals (with justification)
- **Brief Summary of Procedures, to include:**
  - Veterinary care
  - Pain alleviation
  - Euthanasia
- **Summary of Control Model(s)**
- **Brief Summary of Proposed Timeline, to include access to animals**
- **Brief Summary of Research Requiring BSL3/4 Containment**
- **Contact Information for the IACUC Point of Contact**
- **Letter from the IACUC Stating that the Review Has Taken Place and Is Approved**

13. Human Use and/or Human Biological Substances Research Review Summary: Three-page limit. If the proposed study involves human subjects and/or human biological substances, the applicant is ***required*** to submit a maximum of three pages summarizing key aspects of human subjects research that will be conducted. In particular, the following points must be addressed:

a. Human Use

- **Objective of Clinical Study**
  - Briefly describe the purpose/research objective of the clinical study.
- **Brief Summary of Procedure with Timeline**
  - Describe how the key study variables will be measured.
  - Describe the timeline for required study subject visits and list the procedures to be performed at each.
  - Briefly describe the procedures for data and specimen collection, analysis, and evaluation.
- **Proposed Subject Recruitment Process**
  - Describe the target population from which study subjects will be recruited.
  - Provide a scientific rationale for the target sample size.
  - Describe the subject recruitment process, including who will identify potential subjects and how they will be recruited.

- **Proposed Consent Process**
  - Describe the consent process, including when and where the consent interview will take place and the time available for the subjects to consider participation and ask questions.
  - Describe the circumstances under which consent from a legally authorized representative may be required and the process through which it will be obtained.
  - Describe any unusual consent-related issues pertaining to this study.
- **Risk and Intent to Benefit**
  - Describe the most prominent risks involved in study participation (physical, psychological, legal, social, economic, etc.) and the measures that will be taken to minimize and/or manage them.
  - Describe the potential benefits to individual study subjects and to society.
  - Describe the intent to benefit for those subjects unable to provide their own consent, if applicable.
- **Description of the Safety Monitoring Procedures To Be Used in the Protocol**
  - If the study is greater than minimal risk, name the medical monitor and describe his or her role.
  - Define adverse events for this study.
  - Describe the process for reporting serious and unexpected adverse events.
- **Proposed Plan for Study Subject Confidentiality**
  - Describe the strategy for protecting the privacy and confidentiality of research subjects and study data/records.
  - Describe any expected circumstances under which complete confidentiality cannot be guaranteed (e.g., active duty personnel participating in intramural research).
- **Status of FDA Submission (IND, IDE, NDA, PMA, 510K, etc.), if applicable**
  - If the clinical study involves the use of a drug, biologic, or device not yet approved for marketing by the FDA or not yet approved for the indication addressed in the study, state the status of the applicable FDA submission.
  - Identify who will serve as the clinical trial sponsor.
  - Indicate whether the institution has previous experience working with the FDA in developing and conducting clinical trials and provide the location of the regulatory staff who will oversee FDA submissions. Additionally, insure that there is a provision for FDA-required clinical monitoring of the clinical trial.

- **Local Institutional Review Board Requirements**
    - Provide the contact information (name, title, address, email, and phone number) for the IRB point of contact.
    - Provide a letter from the local IRB stating that the review has taken place and is approved (please appended this to the summary).

b. Human Biological Substances

- Provide a detailed description of human biological specimens (e.g., cells, tissues, blood) or the sources of existing biological specimens or cell lines (e.g., commercially purchased cell lines).
- Provide the contact information for the IRB point of contact.
- Provide a letter from the local IRB stating that the review has taken place and is approved.

14. Transition Plan for the Advanced Technology Development Funding Mechanisms: One-page limit. Start the Transition Plan on a new page. Applicants submitting proposals to the Advanced Technology: Product/Technology Down-Selection or Optimization and the Advanced Technology: Clinical Testing/Trials (Human Subjects) Funding Mechanisms ***must*** submit a Transition Plan addressing 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 during programmatic review. Failure to submit a Transition Plan may result in a lower priority rating during programmatic review.

M. Budget Information: Budget information includes the Detailed Cost Estimate form, the Budget Justification form, and the Federal Agency Financial Plan, if applicable, and should be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal's budget justification should include only DOD-funded tasks.

1. Funding Restrictions: Maximum direct costs funding by mechanism:

- Investigator-Initiated Research Award: $625,000
- New and Existing Program Project Award: $1.25M
- Advanced Technology: Product/Technology Down-Selection or Optimization Award: $940,000
- Advanced Technology: Clinical Testing/Trials (Human Subjects) Award: $2.5M

The maximum direct cost can be requested for the performance period. The performance period can be requested for up to 4 years. Indirect costs should be added as appropriate.

2. Detailed Cost Estimate Form and the Budget Justification Instructions: Budget is an important consideration in both peer review and programmatic review, and applicants are

cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. ***Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.*** All costs must be entered in U.S. dollars.
The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project. ***It is expected that institutions will share the cost of equipment purchased for this research proposal. Please see full details under "Major Equipment" in Subsection V.M.2.c.***

Costs proposed must conform to the following regulations and principles:

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

Follow the instructions below when providing the information requested in the Detailed Cost Estimate form.

a. Personnel

i. Name: Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. ***The applicant must be identified as the Principal Investigator of the proposal.***

ii. Role on Project: Identify the role of each participant listed. Describe his or her specific functions in the Budget Justification section of the Detailed Cost Estimate form.

iii. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for

each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the Budget Justification section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

iv. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project. The National Institutes of Health (NIH) salary cap guidelines (http://grants.nih.gov/grants/policy/salcap_summary.htm) can be used as a reference for annual base salaries.

v. Percentage of Effort on Project: The applicant's qualifications and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid collaborators and consultants.

Clinical studies must have a clinical coordinator who has sufficient time dedicated to the project to carry out the record keeping, coordination, and/or other administrative duties the project entails. If the proposed human subject research will be conducted at multiple sites, a separate study coordinator is recommended.

vi. Salaries Requested: Enter the salaries in whole U.S. dollars for each position for which funds are requested. Calculate the salary request by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits for each position may be requested in accordance with institutional guidelines, provided the costs for all sponsors are treated consistently by the applicant's organization. Provide documentation to support the fringe benefits.

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

b. Consultant Costs: Provide the names and organizational affiliations of all consultants whether or not funds are requested.

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

i. If the purchase of equipment for this research project is requested, it is expected that the applicant's institution will share 50% of the cost.

ii. Permanent equipment is any article of nonexpendable tangible property having a useful life of 2 years or longer and an acquisition cost of $5,000 or more per unit.

iii. The basis for the cost of each item of permanent equipment included in the budget must be disclosed.

iv. Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations whose primary purpose is the conduct of scientific research. Normally the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

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

e. Travel Costs: Costs for travel to scientific/technical meetings may not exceed $1,800 per year. Investigators will be invited to present their results at the next Military Health Research Forum meeting. If the award has expired before the meeting is held, funding will be made available for their investigators to participate in the meeting. It is anticipated that the next Military Health Research Forum will be held in May 2008.

Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).

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

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

h. Sub-Contract Costs: A description of services or materials to be awarded by subcontract or subgrant is required. For awards totaling $10,000 or more:

- Identify the type of award to be used (e.g., cost reimbursement, fixed price);
- Identify the proposed subcontractor or subgrantee, if known, and provide an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Specify whether the award will be competitive and, if noncompetitive, provide a rationale to justify the absence of competition; and
- Provide the proposed acquisition price.

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

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals in each budget category for all additional years of support requested and itemize these totals in the Budget Justification section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Directs costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the "Required Files" tab at https://cdmrp.org.

3. Budget Justification (third page of the Detailed Cost Estimate form): Each item in the budget must be clearly justified in the Budget Justification section of the Detailed Cost Estimate form.

4. Federal Agency Financial Plan Requirements: Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

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 before the submission deadline of ***5:00 p.m. Eastern time, May 9, 2006***.

N. Regulatory Requirements: Completed and signed copies of the Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other regulatory documents (see Subsection VII.D.5, Research Involving Human Subjects/Biological Substances/Cadavers; Research Involving Animals Subsection VII.D.4) with the proposal. The applicant should provide these documents to the USAMRMC only upon request.

O. USAMRAA-Required Documents: The Contract Representative at the applicant's institution must upload the current version of the institution's negotiated Rate Agreement, the Certifications and Assurances for Assistance Agreements, and the Representations for Assistance Agreements. These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system by the proposal submission deadline.

P. Submission and Notification Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's Sponsored Programs Office (or equivalent) by the deadline. Unlike other proposals submitted under the BAA 05-1, which can be submitted throughout the year, ***FY06 PRMRP proposals must be submitted electronically by 5:00 p.m. Eastern time on May 9, 2006, 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 FY06 PRMRP is:

Online Letter of Intent:	Expected by ***April 10, 2006***
Online Proposal Information:	Required prior to proposal submission
Proposal Submission/Approval Deadline:	***5:00 p.m. Eastern time May 9, 2006***
Required Supporting Documents:	***5:00 p.m. Eastern time May 9, 2006***
Peer Review (First Tier):	July 2006
Programmatic Review (Second Tier):	September 2006
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:	Anticipated between October 2006 and September 2007

Q. Electronic Submission Requirements: Electronic submission is required. Only proposals submitted as PDF files through the CDMRP eReceipt system at https://cdmrp.org will be accepted.

Several steps are critical to successful proposal submission:

- The Proposal Information must be "Finalized for CR Approval" before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be "Finalized for CR Approval" before the proposal is submitted. The e-mail address of a Contract Representative at the applicant's institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.

- The Contract Representative authorized to negotiate on behalf of the applicant's 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, May 9, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Detailed Cost Estimate form and the Budget Justification form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers differ fundamentally. The first tier is a scientific peer review of proposals against established criteria for determining 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 overall goals of the program.

2. Peer Review: Peer review is conducted by scientific reviewers. The primary responsibility of the peer reviewers 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. Scientific reviewers are selected for their subject matter expertise and experience with scientific peer review.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this supplement.

3. Programmatic Review: Programmatic review is conducted by the JPRP, a team composed of federal and military scientists and clinicians. A function of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. JPRP members base programmatic review primarily on the peer review

summary statements and the proposal abstracts. The JPRP also may review SOWs. Full proposals are not forwarded to programmatic review.

B. Review Criteria

1. Investigator-Initiated Research Awards

- **Research Strategy and Objectives**
  - Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed and appropriate for, and well integrated into, 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 FY06 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?
- **Applicant and Key Personnel Qualifications**
  - Is the applicant appropriately trained and well suited to guide this project?
  - Have the applicant and other key personnel committed a sufficient level of effort to ensure the success of this project?
  - Conversely, are the applicant and key personnel overcommitted on other funded studies?
  - Is the work proposed appropriate to the experience and expertise of the applicant and other researchers (if any)?
  - Are conflicts of interest and commercial interests adequately identified and justified (if applicable)?
  - If the applicant has been funded by the CDMRP in the past, has sufficient progress been made in the funded project?
  - If not, are the reasons why presented adequately (as described in the Applicant Past Performance Summary)?
  - Have collaborations been developed that will support the goals of the project?
  - Have letters been submitted to demonstrate support of the 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 adequate institutional support (space and equipment) provided with the proposal?
- **Animal Research Review**
  - Has the applicant addressed the issues listed in the Animal Research Review Summary document in Subsection V.L.12?
- **Human Biological Substances and Human Subjects Research Review**
  - Has the applicant addressed the issues listed in the Human Subjects Research and/or Human Biological Substances Review Summary in the Human Biological Substances Subsection V.L.13.b and/or Human Subjects Research section Subsection V.L.13.a?
- **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, consultants, 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?

2. New Program Project Awards

- **Research Strategy and Objectives**
  - Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed and appropriate for, and well-integrated into, 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 FY06 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?
- **Applicant and Key Personnel Qualifications**
  - Does the applicant have the training and expertise to oversee the multidisciplinary research of the program?
  - Have the applicant and other key personnel committed a sufficient level of effort to ensure the success of this project?
  - Conversely, are the applicant and key personnel overcommitted on other funded studies?
  - Is the work proposed appropriate to the experience and expertise of the applicant and other researchers (if any)?
  - If an oversight or advisory committee is involved, do its members have the appropriate background to provide sufficient guidance?
  - Are conflicts of interest and commercial interests adequately identified and justified (if applicable)?
  - If the applicant has been funded by the CDMRP in the past, has sufficient progress been made in the funded project?
  - If not, are the reasons for the lack of progress presented adequately (as described in the applicant past performance summary)?
  - Have multidisciplinary collaborations been developed that will support the goals of the program?
  - Have letters been submitted to demonstrate support of the multidisciplinary collaborations?
- **Facilities**
  - Is the scientific environment appropriate for the proposed research?
  - Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?
  - Is there evidence of adequate institutional support (space and equipment) provided with the proposal?

- **Animal Research Review**
  - Has the applicant addressed the issues listed in the Animal Research Review Summary document in Subsection V.L.12?
- **Human Biological Substances and Human Subjects Research Review**
  - Has the applicant addressed the issues listed in the Human Subjects Research and/or Human Biological Substances Review Summary in the Human Biological Substances Subsection V.L.13.b and/or Human Subjects Research Subsection V.L.13.a?
- **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, consultants, equipment costs, or the scope of the research (time or aims)?
  - Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project?
  - Is there a description of how the facility, the program, and investigators will share costs?
- **Focus and Integration**
  - Is there a clear link between the individual research projects, the theme of the program, 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?

3. Existing Program Project Awards

- **Research Strategy and Objectives**
  - Are the hypotheses, experimental design, rationale, methods, and analyses adequately developed and appropriate for, and well integrated into, 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 appropriate) well conceived and likely to lead to subsequent fully developed projects?

- **Impact**
  - Does the proposal address an important problem and directly address the selected FY06 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?
- **Applicant and Key Personnel Qualifications**
  - Does the applicant have the training and expertise to oversee the multidisciplinary research of the program?
  - Have the applicant and other key personnel committed a sufficient level of effort to ensure the success of this project?
  - Conversely, are the applicant and key personnel overcommitted on other funded studies? Is the work proposed appropriate to the experience and expertise of the applicant and other researchers (if any)?
  - If an oversight or advisory committee is involved, do its members have the appropriate background to provide sufficient guidance?
  - Are conflicts of interest and commercial interests adequately identified and justified (if applicable)?
  - If the applicant has been funded by the CDMRP in the past, has sufficient progress been made in the funded project?
  - If not, are the reasons presented adequately (as described in the Applicant Past Performance Summary)?
  - Have multidisciplinary collaborations been developed that will support the goals of the program?
  - Have letters been submitted to demonstrate support of the multidisciplinary collaborations?
- **Facilities**
  - Is the scientific environment appropriate for the proposed research?
  - Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?
  - Is there evidence of adequate institutional support (space and equipment) provided with the proposal?

- **Animal Research Review**
  - Has the applicant addressed the issues listed in the Animal Research Review Summary document in Subsection V.L.12?
- **Human Biological Substances and Human Subjects Research Review**
  - Has the applicant addressed the issues listed in the Human Subjects Research and/or Human Biological Substances Review Summary in the Human Biological Substances Subsection V.L.13.b and/or Human Subjects Research section Subsection V.L.13.a?
- **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, consultants, equipment costs, or the scope of the research (time or aims)?
  - Is there evidence that, where appropriate, arrangements have been made to compensate human subjects/participants for expenses they incur from participating in the project?
  - Is there a description of how the facility, the program, and investigators will share costs?
- **Current Status of the Program**
  - Is a brief description of the current personnel, facilities, and equipment given, including identifying which components will be continued from prior years?
  - If applicable, have changes to the initial program plan and the rationale for changes been articulated?
  - Is there evidence of continued administrative support for the program?
  - If applicable, have recommendations and/or reports from any advisory committees been submitted?
- **Focus and Integration**
  - Is there a clear link between the individual research projects, the theme of the program, 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?

4. Advanced Technology: Product/Technology Down-Selection or Optimization Awards

- **Research Strategy and Objectives**
  - Has the specific technical problem been described?
  - Has the technical feasibility of the proposed research been adequately defined?
  - Has a summary of the research and outcomes confirming proof of principle been provided?
  - Does the product or technology demonstrate sufficient viability to warrant further investment and preclinical testing?
  - Are the study design, methods, and analyses adequately developed and appropriate for, and well integrated into, the aims of the project?
  - Are licensure and regulatory approval risk deemed acceptable?
  - 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?
  - Has a list of target product candidates been selected?
  - Has a well-defined and justified methodology for final down-selection of product candidate been provided?
  - Has capacity to perform Good Laboratory Practice (GLP) studies been identified?
  - Are target deliverables listed in the SOW? If listed, are deliverables and proposed timeline feasible?
- **Impact**
  - Does the proposal address an important problem and directly address the selected FY06 PRMRP topic area?
  - What will be the effect of these studies on the concepts or methods that drive this field?
  - Is the proposed work likely to result in the successful development of an important military health-related product or technology, if successful?
  - What would the impact on the technology development be without continuation of funding beyond the requested performance period?

- **Applicant and Key Personnel Qualifications**
  - Are the applicant and support personnel appropriately trained (to include GLP training) and well suited to guide this project?
  - Has capacity to conduct proposed studies been identified?
  - Are appropriate personnel or other sources of expertise available to successfully complete product/technology development to the stage of development proposed within the performance period?
  - Have the applicant and other key personnel committed a sufficient level of effort to ensure the success of this project?
  - Are conflicts of interest and commercial interests adequately identified and justified (if applicable)?
  - If the applicant has been funded previously by the CDMRP, has sufficient progress been made in the funded project? If not, are the reasons presented adequately in the applicant past performance document?
- **Facilities**
  - Does the scientific environment include GLP-certified facilities 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?
- **Animal Research Review**
  - Has the applicant addressed the issues listed in the Animal Research Review Summary document in Subsection V.L.12?
- **Human Biological Substances Review**
  - Has the applicant addressed the issues listed in the Human Subjects Research Subsection V.L.13.b and/or Human Biological Substances Review Summary in the Human Biological Substances Subsection V.L.13.a?
- **Budget**
  - Is the budget justified and appropriate for the technology development proposed?
  - Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultants, equipment costs, subawards, or the scope of the research (time or aims)?
  - Are other sources of funding adequately described? If there is a need for funding beyond the proposed performance period, have other potential sources of funding (e.g., commercial) to complete the product/technology development been identified?

- Are the appropriate collaborative agreements needed to support the product/technology development established, including funding mechanism for subcontractor, if applicable?

- **Product/Technology Transition Potential (Refer to Product/Technology Transition Plan)**
  - Does the applicant provide adequate details on methods and strategies proposed to ensure continuity for Product/Technology development, to include funding source(s)?
  - Does the applicant provide reasonable and feasible plans for military acquisition of the product beyond PRMRP funding?
- **Prior Accomplishments**
  - Has a summary of previous work on this product or technology been provided?
  - Has previous work, not directly related to the proposed effort but similar, been described?
  - Have changes to the initial development plan and rationale for the changes been described (if applicable)?
  - 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?
- **Required Deliverables (as applicable)**
  - Have the non-GLP animal studies been completed?
  - Have the product candidate(s) been down-selected?
  - Is there a list of alternate technologies with justification and ranking?
  - Has the pre-IND/IDE meeting with FDA been completed, if applicable?
  - Have the GLP studies to support FDA submission been initiated?

5. Advanced Technology: Clinical Testing/Trials (Human Subjects) Awards

- **Research Strategy and Objectives**
  - Is there sufficient evidence that the potential product or technology possesses viability that warrants further investment?
  - Has preclinical safety been demonstrated, and have major safety issues been resolved?
  - Has an acceptable rationale for initiating evaluation in humans been provided, if applicable?
  - Is sufficient information presented to show why the product or technology has a probability of resolving or supporting a military-relevant need or requirement?

- Has a brief summary of competing products or technologies and the cost/benefit of support for this product/technology been provided?
- Have FDA requirements (if appropriate) been met? If not applicable, has applicant provided sufficient justification?
- Are licensure and regulatory approval risk deemed acceptable?
- Has the capacity to manufacture the product under Good Manufacturing Practice (GMP) conditions been established?
- Has the requirement for a successful pre-IND FDA meeting been satisfied, i.e., have the minutes from the pre-IND meeting and a strategy for completing requirements for IND submission, been provided, if applicable?
- Are the incremental steps toward end-product well defined?
- Are the study design, methods, and analyses adequately developed and appropriate for, and integrated into the aims of the project?
- 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?
- Does the SOW address the timeline for IND/IDE/510K/PMA submission to the FDA?
- Are target deliverables listed in the SOW? If listed, are deliverables and proposed timeline feasible?

- **Impact**
  - Does the proposal address an important technical problem and directly address the selected FY06 PRMRP topic area?
  - What effect will these studies have on the concepts or methods that drive this field? What is the likelihood that the resulting product/technology will be fielded (provided to the end-user)?
  - Is the proposed work likely to result in the successful development of an important military health-related product or technology, if successful?
  - What would the impact on the technology development be without continuation of funding beyond the requested performance period?
- **Applicant and Key Personnel Qualifications**
  - Are the applicant and appropriate staff, to include subawardee appropriately trained, certified, and suited to guide this project for commercialization?
  - Do the applicant and appropriate staff, to include subawardee, have sufficient expertise to guide the project through regulatory approvals (IRB, FDA, etc.)?
  - Have the applicant 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 deliver the proposed end-product within the performance period?
- Are conflicts of interest and commercial interests adequately identified and justified (if applicable)?
- If the applicant has been funded previously by the CDMRP, has sufficient progress been made in the funded project?
- If progress on project funded previously was not sufficient, have the reasons for the lack of progress been adequately addressed (as described in the Applicant Past Performance Summary)?

- **Facilities**
  - Is the scientific environment appropriate for the proposed product/technology development?
  - Is there evidence that the product/technology development requirements are adequately supported by proposed collaborative arrangements (if applicable)?
  - Is there evidence of sufficient administrative support provided with the proposal?
  - Is there evidence of adequate institutional support (space and equipment) provided with the proposal?
  - Are GLP, GMP, and Good Clinical Practice (GCP) facilities available?
- **Human Biological Substances and Human Subjects Research Review**
  - Has the applicant addressed the issues listed in the Human Subjects Research and/or Human Biological Substances Review Summary in the Human Biological Substances Subsection V.L.13.b and/or Human Subjects Research Subsection V.L.13.a?
- **Budget**
  - Is the budget justified and appropriate for the technology development proposed?
  - Are there any recommended or required changes that need to be made for personnel, travel, supplies, consultants, equipment costs, subawards, or the scope of the research (time or aims)?
  - Is there evidence that arrangements have been made, where appropriate, to compensate human subjects/participants for expenses they incur from participating in the project?
  - If there is a need for funding beyond the performance period, have other potential sources of funding (e.g., commercial) to complete the product/technology development been identified?

- **Product/Technology Transition Potential (Refer to Product/Technology Transition Plan)**
    - Does the applicant provide adequate detail on methods and strategies proposed to ensure continuity for product/technology development, to include funding source(s)?
    - Does the applicant provide reasonable and feasible plans for military acquisition of the product beyond PRMRP funding?
- **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?
    - Have regulatory issues been addressed, if applicable, (examples include addressing FDA requirements for an investigational new drug or investigational device exemption; use of GMP?
- **Required Deliverables (as applicable)**
    - Has a record of IND/IDE/510K/PMA been submitted to the FDA?

C. 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. Programmatic reviewers also use the following 11 criteria to assist in making their recommendations:

- Peer review recommendations
- Military Relevance Statement (relevance of proposed research to military health)
- Relevance/alignment to selected topic area
- Programmatic priorities, which include congressional guidance, DOD priorities, VA priorities, and collaborations with Federal researchers
- PRMRP portfolio balance
- Budget
- Transition plan for the Advanced Technology Development funding mechanism
- Federal Agency Financial Plan (if applicable)
- Past performance on CDMRP research awards
- Animal Research Review Summary (three-page maximum)

- Human Subjects Research and/or Human Biological Substances Review Summary (three-page maximum)

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.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant will receive notification of the award status of his or her proposal. A copy of the peer review summary statement will be posted to the CDMRP eReceipt system. Applicants can expect to receive notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. An applicant must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations) to be eligible for an award. ***Any organization requesting receipt of an award through this Supplement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.***

Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

A change in institutional affiliation will require the investigator to resubmit the entire proposal packet through his or her new institution to include any regulatory documentation that may require protocols, etc., to be approved for the new institution. The investigator's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting, regulatory review, and a subsequent delay in resuming work on the project. ***Transferring an award that includes a Phase I, Phase II, or Phase III clinical trial will not be permitted.***

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

For multi-institutional studies, collaborating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation to ensure the successful establishment and maintenance of the research project. An intellectual and material property plan agreed to by all participating institutions may be required during award negotiations.

The award start date will be determined during the negotiation process.

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that DOD regulations are met.

2. Certificate of Environmental Compliance: The Certificate of Environmental Compliance must be submitted with the proposal. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents: The Principal Investigator Safety Program Assurance form must be submitted with the proposal.

A Facility Safety Plan is required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

4. Research Involving Animal Use: Specific documents relating to the use of animals in the proposed research will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. Applicants must complete and submit the animal use appendix titled "Research Involving Animals," which can be found on the ACURO website https://mrmc-www.army.mil/rodorpaurd.asp).

Questions related to animal use may be directed to ACURO as follows:

Phone:	301-619-6694
Fax:	301-619-4165
E-mail:	acuro@amedd.army.mil
Mail:	MCMR-ZB-PA 504 Scott Street Fort Detrick, MD 21702-5012

Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

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

a. Requirements: Specific requirements for research involving human subjects, human biological substances, and/or cadavers can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix.pdf.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

It is expected that there will be timely resolutions of human subjects protocols submitted to the investigator's local IRB.

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

b. Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

c. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980) applicable to DOD-sponsored research before writing a research protocol. Title 10 United States Code Section 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is

obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

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

d. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells: Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45, Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g-2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following NIH website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (https://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

e. Clinical Trial Registry: All applicants are required to register clinical trials individually on www.clinicaltrials.gov using the Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: CDMRP-CDMRP Log Number-A, B, C, etc. ***Clinical trials must be registered prior to enrollment of the first patient.*** All trials that meet the definition on the NIH database (see http://prsinfo.clinicaltrials.gov/, click on "Data Element Definitions," see section 6, "Study Phase" and "Study Type") are

required to register, to include all Phase I-IV clinical trials and trials that do not fit into one or more phases, but that are clearly interventional or observational (e.g., some epidemiological or behavioral studies). Address questions on registration to the www.clinicaltrials.gov administrator.

6. Award/Regulatory Approval: The applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written approval from the applicable USAMRMC regulatory office once an award is made. The applicable USAMRMC regulatory office will forward written approvals directly to the applicant.

E. Reporting Requirements: The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full USAMRMC reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

1. Research Progress Reports: Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress reports.

2. Fiscal Reports: Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

3. Non-Exempt Human Studies Reports: For non-exempt human subjects research, documentation of local IRB continuing review (in the intervals specified by the local IRB but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

4. Animal Use Reports: Applicants are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

VIII. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submitting a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

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

C. Information Service: Applicants may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

D. Inquiry Review Panel: Applicants may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

E. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa waiver on behalf of a foreign national in the United States under a J-1 Visa.

IX. ACRONYM LIST

AVI	Audio Video Interleave
BSL	Biosafety Level
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
COI	Conflict of Interest
CR	Contract Representative
DOD	Department of Defense
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HSRRB	Human Subjects Research Review Board
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
JPRP	Joint Programmatic Review Panel
M	Million
MPEG	Moving Picture Experts Group
NIH	National Institutes of Health
NDA	New Drug Application
OMB	Office of Management and Budget
PDF	Portable Document Format
PMA	Premarket Approval
PRMRP	Peer Reviewed Medical Research Program
SOW	Statement of Work
TIFF	Tagged Image File Format
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform