

Appendix A
Letter of Intent
to Submit Proposals in Response to the
FY 99 Department of Defense Prostate Cancer Research Program

Please fill out one of these request forms for each proposal you intend to submit.
Fax this form to (301) 682-5521.

Principal Investigator's Name: _____

Principal Investigator's Address: _____

Phone Number: _____

Fax Number: _____

Intended award category to which the proposal will be submitted (please check ONLY one):

Research Proposals

- New Investigator Award
- Idea Development Award

Training/Recruitment Proposals

- Post-doctoral Traineeship
- Minority Population Focused Collaborative Training Award

Content area that will be addressed in the proposal/project/core (please check a maximum of five areas):

- | | | |
|---|--|--|
| <input type="checkbox"/> Alternative Medicine | <input type="checkbox"/> Gene Expression | <input type="checkbox"/> Prevention |
| <input type="checkbox"/> Behavioral/Social Sciences | <input type="checkbox"/> Gene Sequencing/Mapping | <input type="checkbox"/> Protein-nucleic Acid Interactions |
| <input type="checkbox"/> Biological Response Modifiers | <input type="checkbox"/> Immunologic Sciences | <input type="checkbox"/> Radiologic Sciences |
| <input type="checkbox"/> Cell Biology | <input type="checkbox"/> Health Care Delivery | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Clinical/Experimental Therapeutics | <input type="checkbox"/> Medical Genetics | <input type="checkbox"/> Technology Development |
| <input type="checkbox"/> Endocrinology | <input type="checkbox"/> Molecular Genetics | <input type="checkbox"/> Tumor Biology/Progression |
| <input type="checkbox"/> Epidemiology/Biostatistics | <input type="checkbox"/> Pathobiology | <input type="checkbox"/> Virology |
| | <input type="checkbox"/> Pharmacology/Toxicology | |

Other, please specify _____

Briefly describe your proposed research: _____

Use an additional page if needed. Please include the name of PI and applicant institution for form tracking.

Do you plan to incorporate a Research Award or Training/Recruitment Award into a Prostate Cancer Center Initiation submission? No Yes

Please send me the following:

- Copies of the Proposal Cover Booklet - How many? _____
- Copies of the Proposal Cover Booklet Instructions - How many? _____

Appendix B

Proposal Preparation

Appendix B of this Announcement contains specific instructions for proposal preparation.

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Proposal Preparation

1. Who May Apply

Eligible institutions include for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, and agencies of local, state, and federal governments, including military laboratories. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MIs). Set-asides are provided for these institutions as described in part 22 of this Appendix. Any individual, regardless of nationality or citizenship status, may apply as long as they are employed by or affiliated with an eligible institution.

Investigators are cautioned that awards are made to institutions. Should the PI of a funded project leave the recipient institution, either the PI or an official of the recipient institution should contact the United States Army Medical Research Acquisition Activity (USAMRAA) awarding office as soon as possible to discuss any options available for continued support of the research project.

Set-Aside for Historically Black Colleges and Universities and Minority Institutions

A certain percentage of the total funds allocated for the CDMRP's peer-reviewed research is set-aside to fund proposals from HBCU/MIs. An updated version of the list of the Department of Education recognized HBCU/MIs is posted on the CDMRP website. This list will be used to verify institutional HBCU/MI status. To access this list, enter the website at <http://cdmrp.army.mil>, and then select HBCU/MI List.

HBCU/MI proposals will be reviewed concurrently with all others in the same research category during scientific peer review, but may be evaluated separately during programmatic review when award recommendations are determined. Consistent with the PCRFP's goal, the final investment strategy for HBCU/MI funds will be based upon scientific excellence and program relevance.

2. Proposal Acceptance Criteria

Compliance guidelines have been designed to present the proposal in an organized and easy-to-follow manner to scientific reviewers responsible for reviewing its merit. Scientific merit reviewers will expect to see a consistent, prescribed format for each reviewed proposal. Non-adherence to format guidelines (such as font size, margins, and line spacing) makes proposals

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difficult to read and may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a poorer priority score in peer review. In particular, the review of applications containing more than the allotted number of pages will be restricted to the pages within the page limitations, and excess pages will not be forwarded for peer review.

It is recommended that the instructions in this section be followed carefully. The application should be clear, legible, and conform to the following spacing, font size, margins, and printing guidelines:

- Language: English
- Margins: Minimum of 0.5 inch top, bottom, right, and left
- Paper Size: 8.5 x 11.0 inches (Note to international applicants: A4 paper will be accepted if the text of the proposal does not exceed 7.5 x 10.0 inches [approximately 19 cm x 25.5 cm].)
- Printing: Single-sided (Double-sided printed pages are not accepted, with the exception of article reprints.)
- Spacing: Single-spaced between lines of text, no more than 5 lines of type within a vertical inch
- Type Color: Black ink including all graphs, diagrams, tables, and charts. The application should contain only material that can be photocopied. Submitting investigators should be cautioned that if color graphs or photographs are included, they may not reproduce in subsequent photocopies. Therefore, submission of color figures, tables, graphs, or photographs is not recommended and is at the investigator's own risk.
- Type Density: No more than 15 characters per inch (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Type Font: 12 point, 10 pitch, no more than 15 characters per inch and 114 characters per line

To assist applicants, the following example is included.

This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing.

3. Proposal Cover Booklet (Bubble Sheet)

Complete this form as described in the instruction booklet accompanying the Proposal Cover Booklet.

1. Each proposal should include 1 original plus 3 photocopies of the Proposal Cover Booklet.
2. Proposal Cover Booklets and instructions can be requested via Fax, phone, e-mail, or mail at the following addresses/numbers. Please allow sufficient time for delivery by regular mail.

Fax: (301) 682-5521

Phone: (301) 682-5501

E-mail: cdmrp_pa@ftdetreck-ccmail.army.mil

Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

4. Peer Review Referral Page - Start section on a new page - no page limit

The Peer Review Referral Page should contain the following sections:

1. Proposal Title
2. PI's Full Name, including middle initial
3. Keyword Descriptive Technical Terms. Every effort is made to assign proposals to an appropriate peer review panel. First, please specify which research focus area (i.e., cancer biology, prevention, and/or therapy) will be addressed. Then, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project (e.g., cell signaling, apoptosis, angiogenesis, drug delivery systems, gene therapy, x-ray crystallography, genetic counseling, quality of life, nuclear medicine, immunology, clinical oncology, nutrition).
4. Conflicts of Interest. Every effort is made to avoid real and apparent conflicts of interest during the peer review process. In order to assist the staff in this regard, list the names of all scientific participants in the proposal including the PI, co-investigators, research associates, research assistants, consultants, collaborators, and sub-contractors, and provide the following information for each participant: name, degree(s), scientific discipline or medical specialty (e.g., radiology, immunology, clinical oncology, nutrition,

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pathology, cell biology, and endocrinology), institutional affiliation(s), title(s), and role(s) on proposed project.

5. Proposal Title Page - Start section on a new page - 1 page limit

The Proposal Title Page should include the following information:

1. Proposal Title
2. Award Category
3. PI's full name, including middle initial
4. PI's phone and fax numbers
5. Organization name and location (including city, state, zip or postal code, and country)
6. Contracting Representative's name
7. Contracting Representative's phone and Fax numbers
8. Proposed start date

6. Table of Contents - Start section on a new page - 1 page limit

Prepare a Table of Contents, with page numbers, using the outline provided in the Proposal Preparation section found under each award category. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.

7. Proposal Abstracts - Start each abstract on a new page - 2 page limit

The abstracts are vitally important to the review of the proposal. Both a 1 page maximum technical abstract and a 1 page maximum public (non-technical) abstract are required. Each proposal abstract page should contain the title of the proposal and the name of the PI. The technical abstract should provide a clear and concise overview of the proposed work including the objectives and specific aims of the study, the research design, the study methods, and the relevance of the proposed work to prostate cancer research. The public abstract is intended to increase the education of the non-scientific community. It should be composed in a way to make the scientific objectives of the proposal understandable to non-scientifically trained readers.

Programmatic review is based upon the IP's review of these two abstracts and the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work. Do not include figures in either abstract.

In addition to the abstract pages contained within the proposal, submit 5 additional copies of each of the abstracts in a manila envelope, along with a 3 ½" computer disk containing the abstracts (clearly labeled with the name of the PI, institution, and word processing program). It is recommended that abstracts be written in WordPerfect, Word, or ASCII format. (Note: Abstracts of all funded proposals will be reproduced in a PCRFP abstract book and posted on the CDMRP website (<http://cdmrp.army.mil>). Thus, proprietary information should not be included

in the abstract).

8. Statement of Work - Start section on a new page - 2 page limit

The Statement of Work is a concise re-statement of the research proposal that outlines and establishes the PI performance expectations and timeline for which the USAMRMC will provide financial support. Although some allowance is made for encountering problems and uncertainties that are a part of research, the PI is expected to meet the provisions and milestones of the Statement of Work.

The Statement of Work should be a series of relatively short statements that outline, step-by-step, how each of the major goals or objectives of the proposed research will be accomplished. As appropriate, the Statement of Work should:

1. describe the work to be accomplished as tasks (may relate tasks to specific aims),
2. identify the timeline and milestones for the work over the period of the proposed effort,
3. indicate the numbers of research subjects (animal or human) for each task,
4. identify methods, and
5. identify products/deliverables for each phase of the project.

As a guide, the Statement of Work for a 3-year effort should require approximately 1 page of single-spaced typing. Several sample Statements of Work are included as a reference in Appendix C of this Program Announcement.

9. Proposal Relevance and Impact Statement - Start section on a new page - 1 page limit

In the Proposal Relevance and Impact Statement, the investigator should describe how the proposed research is pertinent to one or more critical issues in prostate cancer biology, prevention, and/or therapy.

10. Proposal Body - Start section on a new page - page limits apply as indicated in individual award categories

Investigators should refer to the specific evaluation criteria listed under the award category to which they are applying to ensure that the necessary information is included. Each award mechanism has specific instructions for the description of the project. Please use the instructions that are provided under each award mechanism for which you wish to apply.

11. References - no page limit

List all relevant references using a standard reference format that includes the full citation (i.e., authors, year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

12. Biographical Sketches - 3 page limit per investigator

Biographical sketches should be prepared for each of the key personnel listed on the budget page including collaborating investigators and mentors. Biographical sketches may not exceed 3 pages per investigator. The “Biographical Sketch” form can be found in Appendix D, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). A list of significant publications and a succinct summary of the investigator’s professional experience in prostate cancer research and/or their potential for contribution to the field of prostate cancer research should be incorporated into the biographical sketch.

13. Existing/Pending Support - no page limit

List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. This proposal should not duplicate other funded research projects.

14. Facilities/Equipment Description - no page limit

Describe the facilities available for performance of the proposed research. Describe the institutional commitment including any additional facilities or equipment proposed for acquisition or available for use at no cost to the USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use.

15. Support Documentation - no page limit

Provide letter(s) from proposed collaborating individuals or institutions confirming collaborative efforts that are necessary for the project's success. Note that other support documentation may also be required within specific award categories. Please follow specific instructions in each award category.

16. Detailed Cost Estimate - no page limit

Use the "Detailed Cost Estimate" form to prepare a detailed cost estimate of the proposed research. This form can be found in Appendix E, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). The cost of preparing proposals in response to this Program Announcement is not considered an allowable direct charge to any resultant grant or contract.

17. Instruments - no page limit

Attach questionnaires, survey instruments, or clinical protocols as they apply to the proposal.

18. Publications and Patent Abstracts - 2 document limit

You may include up to two relevant publication reprints and patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than two such items are included, the extra items will not be forwarded to peer review.

19. Proposal Submission Address

Submit the following documentation to the address listed below:

Proposal: 1 original (binder-clipped) and 30-collated photocopies (stapled or binder-clipped); please do not use rubber bands, spirals, or three-ring binders

Proposal Cover Booklet: 1 original (binder-clipped to the original proposal) and 3 photocopies (*not* binder-clipped to proposal copies)

Letters of Recommendation: If required, binder-clipped to front of original proposal. See individual application instructions.

Abstract Pages: An additional 5 copies of both the technical and public (non-technical) abstracts in a manila envelope along with a 3 ½" computer disk containing the abstract pages which is clearly

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labeled with the name of the PI, institution, and word processing program. It is recommended that abstracts are formatted in WordPerfect, Word, or ASCII format. (Note: The abstracts are vital to the review of the proposal. Abstracts of all funded proposals will be reproduced in a PCRFP abstract book and posted on the CDMRP website (<http://cdmrp.army.mil>.)

Send the Proposal to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRFP99-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702

Please package only **ONE** complete proposal per box. If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with the proposal. This postcard should state the proposal title and PI's name.

20. Proposal Submission Deadlines

The submission deadlines for individual award category proposals solicited in this Announcement are listed under each award category.

Any proposal received after the exact time specified for receipt shall not be considered unless it is received before award is made, and it:

1. was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. was sent by U.S. Postal Service Express Mail Next Day Delivery (Post Office to Addressee: ***Do not use Second Day Delivery***) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal submission deadline, or
3. was placed into the control of commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal submission deadline for delivery by 4:00 p.m. Eastern Time on the due date.

Investigators are advised that documentation of receipt by the delivery agent may be necessary if a problem should occur.

21. Notification

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Following completion of the two-tiered evaluation process, every applicant will receive a letter indicating their funding status, along with a scientific summary critique of their proposal. Scientific review summaries will contain the criteria scores, the global score, and detailed comments that address the proposal's strengths and weaknesses with respect to each evaluation criterion. Notification letters will be sent as official information is available. Thus, not all investigators will be notified at the same time.

Appendix C

Sample Statements of Work

CEPTOR, R.E.

Statement of Work

Development of Peptide Inhibitors of the “Cancer” Receptor

Task 1. To identify the minimal region of the CR polypeptide able to inhibit intact CR when co-expressed in cultured cells (months 1-18)

- develop a series of plasmids for expressing the CR open reading frame (months 1-7)
- perform assays to ascertain which fragments of CR block DNA-binding (months 7-18)
- confirm that fragments of the CR open reading frame that block DNA-binding activity also inhibit CR function in vivo (months 18-24)

Task 2. To identify short peptides modeled after the receptor that act as inhibitors of DNA-binding and subunit association (months 18-36)

- obtain synthetic CR peptides (months 18-21)
- test the effect of synthetic peptides on the DNA-binding activity of CR (months 20-24)
- characterize the inhibitory potency of active peptides and attempt to optimize the effect by testing additional overlapping peptides (months 21-36)
- perform feasibility experiments to assess the ability of selected peptides to inhibit CR function in cultured cells (months 20-36)

Statement of Work

Ultrasound Imaging

Task 1. Modification of ultrasound imaging gantry, Months 1-12:

- a. Modify imaging gantry to permit measurements of the optics.
- b. Perform measurements using a multi-modal scanning configuration.
- c. Design of final optics.

Task 2. Extensive evaluation of ultrasound imaging gantry with the final optics, Months 13-36:

- a. Repeat measurements using the final optics.
- b. Measure the contrast improvement provided by the new detector configuration relative to conventional detector configuration.
- c. Conduct specimen experiments to evaluate the increase in resolution provided by the magnification.
- d. Investigate the extent of artifacts in fixed and scanning modes.
- e. Participate in design of a clinical evaluation study comparing modified ultrasound mammography with conventional mammography.

Statement of Work

Follow-up Care for Men with Prostate Cancer

Task 1. Develop Plan for follow-up patient interviews, Months 1-3:

- a. The tracking system shell from the previous lung cancer project will be modified to track patient recruitment and contact process.
- b. The follow-up patient interview will be pre-screened with prostate cancer patients from our hospital who are not enrolled in our study and modifications will be incorporated.
- c. The environmental process interview (EPI) used for the baseline interview will be adapted for the follow-up interview.
- d. Institutional Review Board approval will be obtained from all hospital sites.
- e. The patient interviewer will be trained in medical terminology, measures of the interview, and use of the modified EPI system.

Task 2. Preparation for Medical Record Abstractions, Months 3-9:

- a. The Medical Record Abstract form will be finalized and the investigator trained to perform patient data reviews using the instrument.
- b. The Medical Record Abstract form will be revised for direct computer data entry.

Task 3. Subject Recruitment and Data collection, Months 9-20:

- a. Patients enrolled in our previous study will be recruited for the proposed follow-up study.
- b. Interviews subsequent to the first follow-up will be modified as necessary to reflect issues relevant to patients beyond the period of adjuvant therapy.
- c. Surveys will be sent to and data collected from enrolled patients every six months.

Task 4. Abstraction of Medical Records, Months 12-24:

- a. Medical record abstractions will be performed for surviving enrolled patients annually.
- b. Data entry and quality control measures will be on-going.
- c. Follow-up interviews will be conducted once annually with surviving enrolled patients over the 4-year study period.

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Task 5. Interim Analyses, Months 24-44:

- a. Interim statistical analyses of data obtained from interviews and medical record abstractions will be performed periodically.
- b. Annual reports will be written.

Task 6. Final analyses and report writing, Months 44-48:

- a. Final analyses of data from interviews and medical record abstractions will be performed.
- b. A final report and initial manuscripts will be prepared.

Biographical Sketches

Provide the following information for the key personnel listed on the budget page for the initial budget period

NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training.)			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. **PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.**

Appendix D

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY.
DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

Appendix D

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY.
DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

Appendix E

Detailed Cost Estimate Instructions

The following sections describe the categories of costs that should be recorded in the detailed cost estimates using the standard budget sheets. All amounts entered should be in U.S. dollars.

1. Personnel

Show projected salary amounts in terms of annual salary and percentage of effort on the project to be charged by the PI, co-investigator(s), research associate(s), and assistant(s), and the total amount per year to be paid to each staff member of the project. Starting with the PI, list the names of all employees of the applicant who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

The qualifications of the PI and the amount of time that he or she and other senior professional key personnel will devote to the research are important factors affecting the selection of research proposals for funding. Grants, cooperative agreements, and interagency acquisitions may be terminated when the PI severs connections with the organization or is unable to continue active participation in the research. Investigators are cautioned that awards are made to institutions. Should the PI of a funded project leave the recipient institution, either the PI or an official of the recipient institution should notify the U. S. Army Medical Research Acquisition Activity (USAMRAA) as soon as possible to discuss any options available for continued support of the research project.

- **Role on Project:** Identify the role of each individual listed on the project. Describe their specific functions in the *Justification* (page 3 of the “Detailed Cost Estimate” form).
- **Type of Appointment (Months):** List the number of months per year reflected in an individual’s contractual appointment with the offering organization. DOD staff assume that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent time, note this with an asterisk (*) and provide a full explanation in the *Justification* (page 3 of the budget form). Individuals may have split appointments (e.g., for an academic period and a summer period). For each appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.

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- **Percentage of Effort on Project:** For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.
- **Salary Requested:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.
- **Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.
- **Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

2. Consultant Costs

Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants, other than those involved in consortium arrangements.

3. 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 separately negotiated.

4. Materials, Supplies, and Consumables

A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, and radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species and the number to be used.

5. Travel Costs

List the number of trips, destinations, and purposes for all proposed travel. Estimate round-trip travel fare and per diem costs for each trip. Travel to scientific meetings requires identification of the meeting and purpose. No more than one trip to a scientific meeting per award per year is funded. Itemize travel requests and justify time in the *Justification* (page 3 of the budget form).

6. Research-Related Patient Costs

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

7. Other Expenses

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

8. Consortium Costs

A description of services or materials that are to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more, provide the following specific information:

1. the identification of the type of award to be used (e.g., cost reimbursement and fixed price);
2. if known, the identification of the proposed subcontractor or subgrantee and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
3. whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
4. the proposed acquisition price.

9. Indirect Costs (overhead, general and administrative, and other)

The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. A copy of the negotiation memorandum should be provided.

Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

10. Budget for Entire Proposed Period of Support (second budget page)

Enter the totals under each budget category for all additional years of support requested and itemize these totals in the *Justification* (on page 3 of the budget form). **Note with an asterisk and explain any significant increases or decreases from the initial year budget. Also, explain any escalations of the budget from the initial to the future year(s) of support.** All amounts should be in U.S. dollars. Total costs for the entire proposed period of support on the last line of this page should agree with the amount entered in #24 of the Proposal Cover Booklet (Bubble Sheet).

11. Budget Justification (third budget page)

Each item in the budget should be clearly justified under *Justification* (on page 3 of the budget form). In addition, for projects with a substantial foreign component, explain and justify this on the *Justification* page.

Detailed Cost Estimate Forms

Principal Investigator *(last, first, middle)*

DETAILED BUDGET FOR INITIAL BUDGET PERIOD					FROM	THROUGH	
PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	% EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	Principal Investigator						
SUBTOTALS ® ® ® ® ®							\$
CONSULTANT COSTS							
MAJOR EQUIPMENT (ITEMIZE)							
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)							
TRAVEL COSTS							
RESEARCH-RELATED PATIENT COSTS							
OTHER EXPENSES (ITEMIZE BY CATEGORY)							
SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD →→→→→							\$
CONSORTIUM COSTS		DIRECT COST					
		INDIRECT COST					
TOTAL PERSONNEL & OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL COSTS FOR INITIAL BUDGET PERIOD							\$

Appendix E

Principal Investigator (*last, first, middle*)

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT						
BUDGET CATEGORY TOTALS*	INITIAL BUDGET PERIOD <small>(FROM FORM PAGE 1)</small>	ADDITIONAL YEARS OF SUPPORT REQUESTED				TOTAL
		2nd	3rd	4th	5th	
PERSONNEL						
FRINGE BENEFITS						
CONSULTANT COSTS						
MAJOR EQUIPMENT						
MATERIALS, SUPPLIES, AND CONSUMABLES						
TRAVEL COSTS						
RESEARCH-RELATED PATIENT COSTS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS						
CONSORTIUM COSTS	DIRECT					
	INDIRECT					
TOTAL DIRECT COSTS						
TOTAL INDIRECT COSTS						
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT THIS AMOUNT SHOULD AGREE WITH THAT ENTERED ON THE COVER SHEET BOOKLET, ITEM #24					\$	

*** Itemize all budget categories for additional years on *Justification* page which follows.**

Appendix E

JUSTIFICATION: FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

Appendix F

Certificate of Environmental Compliance

The Certificate of Environmental Compliance should be executed by the institution's official responsible for environmental compliance.

The Council on Environmental Quality (CEQ) regulations (40 CFR 1500-1508) that implement the National Environmental Policy Act (NEPA) (PL 91-190, as amended) require all federal agencies to examine possible environmental consequences of their proposed and ongoing actions.

The USAMRMC examines all medical research and development projects, whether inside or outside the United States, for their potential environmental impacts. In most cases, contractors conducting research in established laboratories that are in compliance with environmental laws and regulations, or are already covered by existing environmental documentation, will not be required to provide additional information about the environmental impact of their proposed research. Such projects will receive a "categorical exclusion" according to the Army regulations that implement the CEQ regulations (AR 200-2). After a proposal has been selected for award, the USAMRMC will determine if a categorical exclusion is warranted. If there are any extraordinary circumstances surrounding the research [e.g., research that involves the transfer of recombinant deoxyribonucleic acid (DNA) molecules into the genome of one or more human subjects, requires Biosafety Levels 3 and 4, or uses animals captured from the wild], further information may be requested from the investigator to determine the environmental impact of the proposed research. This information should be submitted in a timely manner in order to receive an award.

Appendix G

Research Involving Human Subjects and/or Human Anatomical Substances

Appendix G of this Announcement contains the required approvals, forms, and descriptions for research involving human subjects and/or human anatomical substances (including human organs, tissues, cells, body fluids from human subjects as well as graphic, written, or recorded information derived from human subjects). Address all issues relating to the use of human subjects and anatomical substances in the proposed research

Note that DOD rules for participation of subjects and informed consent differ from those required by other funding agencies.

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Research Involving Human Subjects and/or Anatomical Substances

1. Introduction

In 1991, the DOD, along with 15 other federal agencies, adopted regulations that are known collectively as the Common Federal Rule. These regulations embody the ethical principles of the Belmont Report. Title 32, Code of Federal Regulations, Part 219 (32 CFR 219), “Protection of Human Subjects” applies to all research involving human subjects conducted or supported by the DOD. The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) corollary is 45 CFR 46. Research conducted or funded by the USAMRMC is also governed by Army Regulation (AR) 70-25, January 1990 and Office of The Army Surgeon General (OTSG) Regulation 15-2, January 1989. The USAMRMC also adheres to the Food and Drug Administration’s (FDA’s) regulation, Title 21, Code of Federal Regulations for research involving investigational drugs or devices.

The OTSG maintains the overall responsibility for protecting human research subjects for the Department of the Army (DA).

2. Definitions

2-a. Research

32 CFR 219, The Common Federal Rule, defines “research as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.” Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research

for other purposes. For example, some demonstration and service programs may include research activities.

21 CFR 312 (FDA) defines “clinical investigation” as “any experiment that involves a test article and one or more human subjects.”

2-b. Human Subjects

32 CFR 219 defines “human subject” as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” **The regulations extend to the use of human organs, tissues, cells, body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.**

21 CFR 312 (FDA) defines “human subject” as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.”

3. Human Subjects Research Review Board Process

3-a. Review Levels

In addition to first level of review and approval by the local Institutional Review Board (IRB), the OTSG requires a second level of review and approval by its Human Subjects Research Review Board (HSRRB) of all research involving human subjects. See Section 2-b of this appendix for the definition of a human subject. Approval must be obtained **prior** to initiation of the research protocol.

The HSRRB is functionally similar to a civilian IRB. The HSRRB is supported administratively by the USAMRMC, Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division (HSPD).

If the research proposal is recommended for funding and the research involves human subjects, the HSPD, in accordance with 32 CFR 219, will determine that the research:

1. is exempt from HSRRB review,
2. is eligible for expedited review,
3. is no greater than minimal risk and, therefore, may be administratively reviewed and approved by the HSPD, or

4. is greater than minimal risk and, therefore, requires full HSRRB committee review.

3-b. Timelines and Outcomes

In general, research protocols that pose greater than minimal risk to subjects are submitted through the HSPD to the HSRRB for full committee review and approval prior to implementation of the study. Review and approval by the HSRRB are usually accomplished within 45-90 days after submission of the protocol to the HSRRB. Any revisions to the protocol, consent form(s), advertisements, questionnaires, and other related study documentation recommended by the HSRRB must be reviewed and approved by the Acting Chair, HSRRB **prior to implementation of the study.**

The HSRRB will make one of the following recommendations to The Surgeon General (TSG):

1. approval of proposal without changes,
2. conditional approval of proposal contingent upon changes and/or clarification,
3. deferred (Note: Protocols are deferred when the HSRRB has substantive concerns about the conduct of the protocol or the safety of the subjects. The PI will receive written comments from the HSRRB and the investigator's responses will go to full committee for further deliberation.), or
4. disapproved (Note: The PI will be notified of this decision in writing. The PI must then notify the HSPD of his or her intention to re-submit the protocol or to terminate consideration of the protocol.).

4. Claim of Exempt Research

4-a. Exempt Research Involving Human Subjects or Anatomical Substances

Certain categories of research may be exempt from review by the HSRRB. Those categories are specific and follow federal guidelines. An investigator's research must fit into one or more of the categories in order to file the Claim of Exemption Form.

4-b. Exempt Categories

The following list details the exemption categories.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a) research on regular and special education instructional strategies, or
 - b) research on the effectiveness of or the comparison among instructional techniques,

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- curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if:
 - a) the human subjects are elected or appointed public officials or candidates for public office; or
 - b) Federal statute(s) requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 4. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 5. Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and that are designed to study, evaluate, or otherwise examine:
 - a) public benefit or service programs,
 - b) procedures for obtaining benefits or services under those programs ,
 - c) possible changes in or alternatives to those programs or procedures, or
 - d) possible changes in methods or levels of payment for benefits or services under those programs.
 6. Taste and food quality evaluation and consumer acceptance studies:
 - a) if wholesome foods without additives are consumed, or
 - b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4-c. Claiming Exemption

Complete the form in Section 10 of this appendix to claim exemption for research involving human subjects or anatomical substances.

4-d. Final Judgment

The HSPD retains final judgment as to whether a particular activity is covered by this policy.

5. Guidelines for Writing Research Protocols Involving Human Subjects

5-a. The Basic Protocol

A detailed research protocol is required for the HSRRB review of your research. All submissions should include the following information:

1. **Project Title.** The consent form title should match that of the project.
2. **Phase.** For Food, Drug, and Cosmetic Act-regulated medical products, designate as a Phase I, II, III, or IV protocol.
3. **Principal Investigator.** The complete name, address, and phone number of the PI should be listed.
4. **Location of Study.** List all centers, clinics, or laboratories where the study is to be carried out. The complete addresses and site investigator(s) should be listed.
5. **Time Required to Complete.** The month and year of expected start and completion should be listed.
6. **Objectives.**
7. **Study Population.** Detail source, number, age range, and sex of subjects along with inclusion/exclusion criteria.
8. **Protocol Design.** Outline the proposed methodology in enough detail to show a clear course of action. Technological reliability and validity of procedures should be indicated. Minimum guidance for the plan includes:
 - a) Subject identification (Describe code system to be used.)
 - b) Subject assignment
 - c) Evaluations prior to entry

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- d) Evaluations to be made during the conduct of the study (i.e., laboratory evaluations, specimens to be collected, schedule and amounts, storage to include where and whether special conditions are required, labeling and disposition)
 - e) Clinical Assessments (i.e., schedule of clinical evaluations and follow-up procedures, and adverse events)
9. **Risks/Benefits Assessment** (Detail benefits of the research to the subject, precautions to be taken to minimize and/or eliminate risks, and specific medical or nursing care that will be needed.)
10. **Reporting of Serious and Unexpected Adverse Events.** (See HSPD Clause 001.02.- Section 5-b.i. of this appendix)
11. **Description of Protocol Drug(s) or Device(s).** If the protocol uses an investigational drug or device, provide the following information:
- a) Investigational New Drug (IND)/Investigational Device Exemption (IDE) number and sponsor
 - b) Complete names and composition of all medication(s), device(s), or placebo(s)
 - c) Source of medication(s), device(s), placebo(s)
 - d) Place where study medication(s) will be stored
 - e) Dose range, schedule, and administration
 - f) Washout period (The washout or pre-drug period must be noted carefully.)
 - g) Duration of drug or device treatment
 - h) Concomitant medications
 - i) Antidotes and treatments available
 - j) Disposition of unused drug
12. **Disposition of Data.** Describe where the data will be stored and for how long. **Note:** Records for IND studies must be kept until 2 years after a New Drug Application (NDA)/license for the investigational drug is approved/issued, or for 2 years after the IND is withdrawn. Records required for IDE studies should be retained for 2 years after the latter of the following dates: the date that investigation is terminated or completed; or the date that records are no longer required for support of a premarket approval application.
13. **Modification of the Protocol.** Describe the procedure to be followed if the protocol is modified.

14. **Roles and Responsibilities of Study Personnel.** Briefly describe the duties of study personnel.
15. **Signature of Principal Investigator.** Type the following statement, “I have read the foregoing protocol and agree to conduct the study as outlined herein.” The PI should sign and date following this statement.

5-b. Requirements Unique to DOD/USAMRMC-Funded Research

5-b.i. Reporting of Serious and Unexpected Adverse Events

HSPD Clause 001.02

Serious and unexpected adverse experiences will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality [(301) 619-2165, during non-duty hours call (301) 619-2165 **and** send information by fax to (301) 619-7803]. A written report will follow the initial telephone call within 3 working days. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012.

HSPD Clause 007.01

An adverse event temporally related to participation in the study should be documented whether considered to be related to the test article. This definition includes intercurrent illnesses and injuries, and exacerbations of pre-existing conditions. Include the following in all IND safety reports: Subject identification number and initials; associate investigator’s name and name of hospital or medical treatment facility; subject’s date of birth, gender, and ethnicity; test article and dates of administration; signs/symptoms and severity; date of onset; date of resolution or death; relationship to the study drug; action taken; concomitant medication(s) including dose, route and duration of treatment, and date of last dose.

5-b.ii. Volunteer Registry Data Base

HSPD Clause 002.01

It is the policy of the USAMRMC that data sheets are to be completed on all volunteers participating in research for entry into this Command’s Volunteer Registry Data Base. The information to be entered into this confidential data base includes name, address, social security number, study name, and dates. The intent of the data base is twofold: first, to readily answer questions concerning an individual’s participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

5-b.iii. Sample Donation

HSPD Clause 004.01

If the samples donated in this study will be used in other studies, the statement “I understand that there is a possibility that the blood, tissue, body fluid, product, or sample(s) (specify type) which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability should be included in the consent form.” In addition, a donation form must be prepared for signature by the volunteer and a witness that states “I voluntarily and freely donate any and all blood, tissues, body fluid, product, or sample(s) (specify type) to the study sponsor (insert institution name) and hereby relinquish all right, title, and interest to said items.” The title of the study should be inserted at the top of this donation form. The samples which will be stored should contain no personal identifiers.

5-b.iv. Title 10 United States Code, Section 980

HSPD Clause 006.01

10 United States Code 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

5-b.v. Medical Monitor

HSPD Clause 008.01

A medical monitor must be assigned to any study involving greater than minimal risk to subjects. The name and curriculum vitae of the medical monitor must be provided. This individual should be a qualified physician, other than the Principal Investigator, not associated with this particular protocol, able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and who will monitor the subjects during the conduct of the study.

5-b.vi. Serum Pregnancy Testing

If pregnant subjects will be excluded from participation in the study, the **method of determining pregnancy** status in women of childbearing potential must be specified. Also, the time that will elapse between the pregnancy test and exposure to research procedures or medical products must be documented. Serum pregnancy tests are required for all clinical medical product studies. For IND studies, serum or urine pregnancy testing is required within 48 hours prior to the start of the study.

5-c. Advertisements, Posters, Flyers, or Press Releases to Recruit Subjects

If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the local IRB-approved advertisement must be provided. For studies involving investigational drugs or devices, local IRB review of advertisements is necessary to ensure the information is not misleading to the subjects participating in IND or IDE studies. The FDA has established guidelines on advertisements for subjects. General guidance includes: name and

address of PI, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.

5-d. Surveys, Questionnaires, or Other Instruments

If the research involves surveys, questionnaires, or other instruments, include copies of the instruments.

5-e. Investigational Drugs or Devices

For research that involves an investigational drug or device:

1. Submit a copy of the Investigator's Drug Brochure and/or device manual and associated case report/data collection forms.
2. For IND products, specify the IND number, name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 312.
3. For Investigational Devices, include your local IRB's assessment of the risk of the investigational device you plan to use in your study. If the device poses significant risk to research subjects, specify the IDE number obtained from the FDA, the name of the sponsor, and the procedure by which the IDE sponsor will monitor the protocol in accordance with 21 CFR 812.
4. Contact your local IRB and/or the FDA if you have questions regarding IND or IDE submission requirements.

6. Informed Consent Requirements

The information that is given to the subject or his or her representative shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

6-a. Elements of Informed Consent

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The following information is essential for informed consent documents:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, include the following explanation of medical care available for research-related injury (HSPD Clause 003.01):

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Four possible mechanisms are available to offset the costs of this requirement:

- a) The proposed recipient may absorb such costs into the institution's operating budget.
- b) The proposed recipient's liability insurance, if available, may be sufficient to cover any medical care costs. The proposed recipient's business office and/or legal advisor must ensure that there is adequate coverage under this liability insurance.
- c) The proposed recipient could negotiate an additional amount of funds, if available, into the award that will cover such medical care cost (such as liability insurance).
- d) Third-party payers may be billed for such medical expenses. If this method is used, the subject must be informed, in the consent document, that his or her insurance company will be billed.

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7. The name of the investigator as a point of contact for answers to questions about the research and research subjects' rights, and the name of the IRB contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

6-b. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

6-c. Requirements Unique to DOD/USAMRMC-Funded Research

6-c.i. Certification of Translation

HSPD Clause 005.01

Provide documentation that the foreign language version of the consent form is an accurate translation. Documentation should include the following statement, "I certify that this is an accurate and true translation" as well as the signature, name, address, phone number and, if available, fax number of the translator.

6-c.ii. Payment for Study Participation: Active Duty Military Personnel

Under 24 CFR 30, payment for participation is limited to blood donation and may not exceed \$50 per blood draw. Active duty research subjects may not receive any other payment for participation in a research study.

6-c.iii. Confidentiality: Military Personnel

The following statement is **MANDATORY** for studies utilizing military personnel:

All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

6-c.iv. Pregnant Women

If pregnant women will be excluded, the following statement, HSPD Clause 009.01 (or equivalent), must be included:

I should avoid becoming pregnant for at least (time period in days, weeks, or months) after participation in the study. To avoid becoming pregnant, I should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm-killing products are not totally effective in preventing pregnancy.

6-c.v. Volunteer Registry Data Base

For all studies involving greater than minimal risk, HSPD Clause 002.01, Volunteer Registry Data Base, must be included in the consent form. See Section 5-b.ii. of this appendix.

7. Assurances

If an institution has filed a Multiple Project Assurance (MPA) with the DHHS Office for Protection from Research Risks (OPRR), that assurance number should be documented on the Optional Form 310 (OF 310, Protection of Human Subjects Assurance/Certification/Declaration, page G-19), which replaced DHHS Form 596.

If the institution has not filed a MPA with OPRR, a written Assurance of Compliance should be filed with the USAMRMC Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division. A DOD Assurance number will be issued for the research project. There are three different assurance applications: (1) for institutions that have an

IRB but no MPA; (2) for overseas institutions; and (3) for institutions using another institution's IRB. Sample assurance documents and the OF 310 can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>).

The OF 310 should be completed and signed by the Chairperson of the IRB. If another agent signs this document, verification of authority should be included in the remarks column (individual's signature authority). The OF 310 **must** include the level of risk that the project poses to the subject. These risk levels are: exempt, minimal risk, and greater than minimal risk. The HSPD reserves the right to determine whether the assigned risk level is in compliance with all applicable regulations.

8. Inclusion of Women and Minorities in Research

Consistent with the Belmont Report and recent Congressional legislation, special attention is given to inclusion of women and minorities in research funded by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. If women and/or minorities will be excluded, a justification must be included.

9. Where to Go for Help and Information

If your research involves human subjects, you should first contact your local IRB for institutional requirements.

If you have questions regarding the USAMRMC protocol and consent form requirements or the review and approval process, contact the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division at the address or phone number listed below:

Phone: (301) 619-2166
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-HR
504 Scott Street
Fort Detrick, MD 21702-5012

References:

- Title 32 Code of Federal Regulations, Part 219, Protection of Human Subjects
- Title 21 Code of Federal Regulations, Part 50, Protection of Human Subjects
- Title 21 Code of Federal Regulations, Part 56, Institutional Review Boards
- Title 21 Code of Federal Regulations, Part 312, Investigational New Drug Application
- Title 21 Code of Federal Regulations, Part 812, Investigational Devices
- Army Regulation 70-25, Use of Volunteers as Research Subjects
- Army Regulation 40-7, Use of Investigational Drugs and Devices in Humans and the Use of

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Schedule I Controlled Drug Substances

- Office of The Surgeon General Regulation 15-2, Human Subjects Research Review Board
- Title 45 Code of Federal Regulations, Part 46 (45 CFR 46), Subparts B, C, and D, Protection of Human Subjects
- Title 10 United States Code, Section 980
- Department of Defense Directive 3216.2
- Department of Defense Directive 6465.2 (when using organs or tissues obtained at autopsy)

Copies of the preceding references can be obtained from either the U.S. Government Printing Office or the National Technical Information Service at:

Phone: (202) 512-1800

Mail: U.S. Government Printing Office
North Capitol & G Streets, NW
Washington, DC 20401

Phone: (703) 487-4650 or 4684

Mail: National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161

10. Claim of Exemption from Review by the Human Subjects Research Review Board

United States Army Medical Research and Materiel Command
 Office of the Deputy Chief of Staff for Regulatory Compliance and Quality
 Human Subjects Protection Division

PROTOCOL TITLE
PI'S NAME
INSTITUTION

EXEMPT CATEGORY CLAIMED (Please refer to Exempt Categories - Section 4-b. in this Appendix)

1. Will existing or archived data, documents, records, or biological specimens be used?

	—	—
	Yes	No

 - a. Will any data or biological specimens be collected from subjects?

	—	—
	Yes	No
 - b. What is the source(s) of existing or archived data/biological specimens? (all that apply)

— existing data	publicly available?	—	—
		Yes	No
— archived data	publicly available?	—	—
		Yes	No
— biological specimens	publicly available?	—	—
		Yes	No
 - c. Will the information be recorded in such a manner that subjects cannot be identified, directly or indirectly through links?

—	—	—
	Yes	No
2. Will data be recorded?

	—	—
	Yes	No

 - a. by audiotape?

	—	—
	Yes	No
 - b. by videotape?

	—	—
	Yes	No
3. If survey instruments are used, will sensitive or private topics be explored?

	—	—
	—	Yes
4. Will the subjects be identifiable either by name or through demographic data? If yes, describe on a separate sheet how the confidentiality of a subject's identity will be maintained and plans for maintaining or destroying identifying links to subjects after the study is completed.

	—	—
	Yes	No

 PI's Signature

**Protection of Human Subjects
 Assurance Identification/Certification/Declaration
 (Common Federal Rule)**

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the common rule. See section 101(b) the common rule for exemptions. Institutions submitting applications or proposals for support must submit certification or appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the common rule.

Institutions with an assurance of compliance that covers the research to be conducted on file with the Department, Agency, or the Department of Health and Human Services (HHS) should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. Institutions which do not have such an assurance must submit an assurance and certification of IRB review and approval within 30 days of a written request from the Department or Agency.

1. Request Type <input type="checkbox"/> ORIGINAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER: _____	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project (Respond to one of the following)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
 Assurance identification no. M-_____ IRB identification no. _____
- This Assurance, on file with (*agency/dept*) _____, covers this activity.
 Assurance identification no. _____ IRB identification no. _____ (*if applicable*)
- No assurance has been filed for this project. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the common rule and any other governing regulations or subparts on
 (date) _____ by: Full IRB Review or Expedited Review
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.		10. Name and Address of Institution	
11. Phone No. (<i>with area code</i>)	12. Fax No. (<i>with area code</i>)	14. Title	
13. Name of Official			

15. Signature	16. Date
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Appendix H

Research Involving Animals

Appendix H of this Announcement contains the required approvals, forms, and descriptions for research involving animals. Address all issues relating to the use of animals in the proposed research. (Research conducted under sponsorship of the USAMRMC that generates pre-clinical safety data intended to support a research or marketing permit for products regulated by the Food and Drug Administration will be in conformance with the Good Laboratory Practices Regulations.) Please note that DOD procedures for reviewing and approving the use of animals in research differ from those required by other funding agencies.

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Research Involving Animals

1. Introduction

If using animals, provide all information required by this appendix. Any and all subcontractors using animals must also provide the information required by this appendix.

DOD definition of animal: Any live nonhuman vertebrate.

Appendix H

The DOD Directive 3216.1, dated April 17, 1995, provides policy and requirements for the use of animals in DOD-funded research. **These requirements may differ from those of other funding agencies.** Each of the following items **must be** addressed in a proposal appendix entitled “Research Involving Animals.” Questions concerning animal use should be directed to:

Phone: (301) 619-2144
Fax: (301) 619-4165
Mail: U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick, MD 21702-5012

2. Alternatives to Painful Procedures

A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied.

A written narrative description of the methods and sources used to search for alternatives to painful procedures, including alleviated pain, **must** be provided. The minimal written narrative must include: the databases searched or other sources consulted, the date of the search and the years covered by the search, and the key words and/or search strategy used by the principal investigator when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to the painful or distressful procedure. Where Federal law requires specific testing procedures, the CFR references or other legal guidelines requiring them should be noted. (The USAMRMC reserves the right to request evidence that a literature search for alternatives to painful procedures was performed.)

3. Rationale for Using Animals

Provide a rationale for using animals in the proposed research. Explain what alternatives to animal use were considered, such as computer modeling or cell cultures, and explain why these alternatives cannot be used to obtain the research objectives. **It is USAMRMC policy that alternatives to the use of animals be thoroughly investigated prior to submission of any proposal involving animals.**

4. Species Identification and Rationale

Identify the species of animals to be used and provide a rationale for their use. Explain why this particular animal model(s) was chosen over other animal models.

5. Rationale for the Number of Animals Required

Provide the **number of each species of animals** to be used by experimental design. Justify these numbers either **scientifically or mathematically**. **Show how these numbers were determined to be the minimum** required to obtain valid results.

6. Experimental Design

Provide a complete description of the proposed use of the animals by experimental design. Include surgical procedures, biosamples (frequency, volume, harvest site, and method of tissue collection), adjuvants, and other injections (agent, dosage, route, and anatomical site of administration).

7. Anesthesia/Analgesia/Tranquilization

Describe what anesthetics, tranquilizers, and analgesics will be used by agent, dosage, route, and anatomical site of administration. If none are to be used, provide an explanation.

8. Study Endpoint

Describe the projected endpoint or termination of the study for the animals.

9. Euthanasia or Final Disposition

Describe the method of euthanasia by agent, dosage, route, and anatomical site of administration. If animals are not euthanized, state final disposition of the animals.

10. Institutional Animal Care and Use Committee(s) (IACUC) Approval

Provide evidence of protocol approval from the IACUC of the institution where animal research will be performed including any subcontracting facility. If it was not possible to have the protocol reviewed by the Committee prior to submission of the proposal, then so state. Evidence of committee review can follow proposal submission, but must be provided prior to award. **RESEARCH WILL NOT BE FUNDED WITHOUT EVIDENCE OF APPROVAL FROM THE IACUC(s).**

11. U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service Animal Care Inspection Report

Include a copy of the most recent USDA Inspection Report for any and all facilities where animal research will be performed, including any subcontracting facility.

12. Qualifications

Provide information on the qualifications and training of personnel performing the animal procedures. This information must specifically address the training and experience these personnel possess in using and manipulating the species of animals detailed in the proposal.

13. Accreditation

One of the following must be provided for each facility where the animal research will be conducted:

1. Evidence that the facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
2. A copy of the Institutional Letter of Assurance of Compliance with the “Public Health Service Policy on Humane Care and Use of Laboratory Animals,” revised September 1986.
3. A statement signed by the Institutional Official that the care and use of animals will be performed according to the National Research Council 1996 “Guide for the Care and Use of Laboratory Animals” and applicable Federal regulations.

14. Principal Investigator Signed Assurances

The principal investigator must provide the following signed assurances (this page may be photocopied and signed):

1. I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.
2. I assure that the animals authorized for use in this protocol will be used only in the activities, manner, and quantities described herein, unless a deviation is specifically approved by my IACUC and the USAMRMC Animal Use Review Division.
3. I accept full responsibility for the proper care and use of the animals during the conduct of research outlined in the proposal.
4. I verify that I have made a reasonably good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

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5. I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent in those procedures and have received training on the use of animals in research as required by the Animal Welfare Act of 1985.
6. I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal and that the minimum number of animals needed for scientific validity will be used.

Principal Investigator's Signature

NOTE: For proposals that require the use of nonhuman primates, companion animals, marine mammals, or for research deemed sensitive by the USAMRMC, a site visit shall be conducted as necessary by the USAMRMC Animal Use Review Officer or designees.

Appendix I

Safety Program Plan

Appendix I of this Announcement contains the required assurances, approvals, forms, and descriptions relating to safety.

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Safety Program Plan

Each of the applicable items below must be addressed in a proposal appendix entitled “Safety Program Plan” and must be prepared specifically for the proposal. Each section should be operation/research specific and addressed in order.

Institutional safety manuals may be referenced; however, **do not send copies of Facility Safety Plan (FSP) or Standard Operating Procedures (SOPs)**. A list of program contents with a brief description of each item (maximum 3 pages) is acceptable. If not applicable, so state. Provide a **website address**, if available, for additional safety and occupational health information.

Those items that do not apply to the proposed research will be labeled as “not applicable” or “N/A.”

1. Affirmation of Safety

The PI (recipient) shall submit the following paragraph as affirmation that a safety program is in place and in accordance with all applicable regulations.

(Recipient name) affirms that there is an existing safety program that is in accordance with appropriate Federal, State, and Local regulations, as required by the Occupational Safety and Health Act; that hazards have been identified, eliminated, and/or controlled; and that research may be performed safely under laboratory conditions. (Recipient name) shall be held responsible and liable for inaccuracies of the information provided, failure

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to implement an effective safety and occupational health program, and/or adverse conditions that may result from the failure of the recipient to identify hazard information.

Signature of Recipient, Date

2. Research Operations/Standard Operating Procedures (SOPs)

Safety procedures relating to the research operation. These should include but are not limited to the following: description of safety procedures for performing the protocol; description of any special skills, training, and SOPs to assure safe research operations (Safety Committee, HAZCOM, Bloodborne Pathogen, and Chemical Hygiene, etc.); and description of medical surveillance and support.

3. Facility Equipment and Description

This should include a description of any biological safety cabinets, ventilation system employed, and personal protective equipment.

4. Hazard Analysis

Include a description of each hazard identified, hazard analysis based on maximum credible event, and plan to minimize or eliminate hazards (infection, toxic substance, and biological hazards).

5. Radioactive Materials

If radioactive materials are used, the materials and the disposal method should be identified. A copy of the Nuclear Regulatory Committee (NRC)-state-approved license or agreement shall be submitted. If no such material is to be used, it should be so stated.

6. Recombinant DNA

Research involving recombinant DNA must meet or exceed NIH Guidelines for Research Involving Recombinant DNA Molecules, January 1997 edition. Include a written approval letter from the organization's Institutional Biosafety Committee (IBC). The IBC reviews all applications to perform protocols involving recombinant DNA (biohazardous material). If not applicable, it should be so stated.

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Copies of the NIH Guidelines are available at:

Fax: (301) 496-9839
Phone: (301) 496-9838
E-mail: www.nih.gov/od/orda
Mail: Office of Recombinant DNA Activities
National Institutes of Health, MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda, MD 20892-7010

7. Biological Defense Program Requirements

- Contractors performing work with **Biosafety Level-3 and 4** material must prepare a safety plan in accordance with 32 CFR 626.18.
- Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of Biological Defense Program (BDP) activities and the appropriate support necessary, to include any equipment and training to provide effective emergency response. Agreements with external agencies must be formalized. (For the purpose of this requirement, the term “local emergency support agencies” refers to any agency that could reasonably be expected to have some capability to provide timely and effective support in the management or resolution of a biological mishap arising from BDP operations.) **A copy of this agreement must be submitted with the proposal.**

- **(Sample)**

Local Emergency Support

(Police, Fire, Health Department), is fully aware of the research program entitled _____ in the Department of _____ at _____, which is supported by the U.S. Army Medical Research and Materiel Command (Contract Number _____). In the event that a situation requires our response, we are equipped and prepared to handle those emergencies as appropriate for this project.

Acknowledged:

Name	Title (e.g., Fire Chief)	Date
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- The PI is directly responsible and liable for all aspects of research project safety and ensures that all Facility Safety Plan requirements are in compliance with 32 CFR 626 and 627 (Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements).

Appendix J

General Information

Appendix J of this Announcement contains general information relating to USAMRMC policies and procedures.

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General Information

****Important Note Regarding Amended Proposals****

Re-submissions of previously reviewed proposals are acceptable. However, the applicant should be cautioned that the year-to-year status of funding for the PCRCP does not permit the establishment of standing panels for peer review. Therefore, the re-submission of a revised proposal does not guarantee any funding advantage or an improved priority score. Re-submitted/amended proposals should meet the requirements for the appropriate award category in the current Announcement and adhere to this year's format guidelines.

1. Policy and Procedures

1-a. USAMRMC Award

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Proposals selected for funding are processed by the USAMRAA.

All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institute,

commercial firm, or Government agency (including military laboratories) in order to receive support.

1-b. Historically Black Colleges and Universities and Minority Institutions

Colleges and universities that qualify as HBCU/MI are determined by the Department of Education to meet the requirements of 34 CFR Subpart 608.2 or 34 CFR Subpart 607.2. An updated version of the list of the Department of Education recognized HBCU/MI is posted on the CDMRP website. This list will be used to verify institutional HBCU/MI status. To access the list, go to <http://cdmrp.army.mil>, then select HBCU/MI list.

1-c. Procurement Integrity, Conflicts of Interest, and Other Improper Business Activities

The Procurement Integrity Act, Title 41 United States Code 423, et seq., contains prohibitions against certain activities between offerors and Government officials. Any questions regarding these prohibitions should be directed to the USAMRMC legal staff at (301) 619-2065. Proposed military/civilian collaborations should pay special attention to the Procurement Integrity Act.

1-d. Disclosure of Information Outside the Government

By submission of an application, the applicant understands that disclosure of information outside the Government shall be for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized. Funded projects may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.

1-e. Award Eligibility

To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110).

1-f. Government Obligation

PIs are cautioned that only an appointed Contracting/Grant 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. A PI who, or an organization that, makes financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grant Officer does so at their own risk.

1-g. Information Service

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

1-h. Funding Instrument

All awards under this Announcement are anticipated to be grants or cooperative agreements. More information on these funding instruments may be obtained on request from:

Fax: (301) 619-2937

Mail: Director

U.S. Army Medical Research Acquisition Activity

ATTN: MCMR-AAA

Fort Detrick, MD 21702-5014

1-i. Inquiry Review Panel (IRP)

Applicants to this Announcement can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the Congressionally Directed Medical Research Programs staff, USAMRMC judge advocate general staff, and USAMRAA contracting officers constitute an IRP and review each inquiry to determine whether factual or procedural errors in either level of review have occurred, and if so, what action should be taken.

2. Research Administration

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

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

Appendix K

Acronyms Used in this Program Announcement

AAALAC-I	Association for Assessment and Accreditation of Laboratory Animal Care - International
AR	Army regulation
CDMRP	Congressionally Directed Medical Research Programs
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CG	Commanding General
DA	Department of the Army
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic acid
DOD	Department of Defense
EPI	Environmental Process Interview
ET	Eastern Time
FDA	Food and Drug Administration
FSP	Facility Safety Plan
FY	Fiscal year
HSPD	Human Subjects Protection Division
HSRRB	Human Subjects Research Review Board
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IP	Integration Panel
IRP	Inquiry Review Panel
IUD	Intrauterine device
MI	Minority Institution
MPA	Multiple Project Assurance
NDA	New Drug Application
NEPA	National Environmental Policy Act
NIH	National Institutes of Health
NRC	Nuclear Regulatory Committee
OMB	Office of Management and Budget
OPRR	Office for Protection from Research Risks
OF	Optional Form
OTSG	Office of The Surgeon General of the Army
PCC-PI	Prostate Cancer Center – Principal Investigator
PCRP	Prostate Cancer Research Program
PI	Principal Investigator
PL	Public Law

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RCQ	Regulatory Compliance and Quality
SOP	Standard operating procedure
USAMRAA	United States Army Medical Research Acquisitions Activity
USAMRMC	United States Army Medical Research and Materiel Command
USDA	United States Department of Agriculture