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USAMRMC

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

Col. Rich 1-24-98

FY97 - 1 mos faster

G-1 Rpt - Now will be ready
30th Apr -
Rpt. on Streamlining
procurement.

FY98 - \$ spent as part
of FY97 process.

Will need to use some of
FY98 \$ to fund 25% of
FY97.

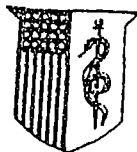
Have speeded up 97 awards
moved mkt from end of Apr to
mid March.



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EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

10/10/97

WASHINGTON, D.C. 20500

Lt. Gen Ron Blanck

703-681-3000.

Walter Reed - Imaging Ctr
of Excellence

Ultra-fast CT

Volume-Angio-CT

U.S. Army Medical Research
& Material Command

Brig. Gen Russ Sidechuck^{sq?}

Chris Eisemann

George Smiley

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CANCER FACTS & FIGURES-1997



Estimated number of new cancer cases in 1997 by state, total: 1,382,400 (excluding Puerto Rico).
 Estimates for Puerto Rico are based on 1990-1991 data from the Central Cancer Registry of Puerto Rico.
 *Excluding basal and squamous cell skin cancer and carcinoma in situ except bladder.



DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
524 PALACKY STREET
FORT DETRICK, MARYLAND 21702-5024

REPLY TO
ATTENTION OF.

July 15, 1997

Dear Colleagues:

This Broad Agency Announcement (BAA) for the Department of Defense Prostate Cancer Research Program represents the combined efforts of many concerned individuals and groups committed to addressing a health problem that touches all men who are struggling with prostate cancer, their families, and friends. The investment strategy for this research embodies the collective wisdom of some of this country's most distinguished medical scientists and practitioners.

The BAA reflects the commitment of the U.S. Army Medical Research and Materiel Command to continue managing a program responsive to the vision and equal to the dedication of all members of the prostate cancer community. The ultimate success of this unique and important venture depends upon your submission of innovative ideas and proposals, with a thorough process of review and evaluation.

My staff and I stand prepared to answer your questions and assist you in the preparation and submission process. Join with us in continuing to support and fund the best programmatically relevant science to challenge disease, sustain health, and improve the quality of life for those with prostate cancer.

Sincerely,

A handwritten signature in cursive script, reading "Russ Zajtchuk", is written over the typed name.

Russ Zajtchuk
Brigadier General, Medical Corps
Commander

FOREWORD

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed by the Secretary of the Army to initiate the Department of Defense (DOD) Prostate Cancer Research Program (PCRP). The deadlines, format, and other criteria specified for proposals in this Broad Agency Announcement (BAA) are based on program objectives, public needs, and acquisition regulations.

Section I of this announcement summarizes the program focus, award categories, funding mechanisms, and funding levels. This information is based, in part, on the June 1997 recommendations of the DOD PCRP Integration Panel.

Section II describes the USAMRMC process for scientific and programmatic evaluation and lists evaluation criteria for each award category solicited by this BAA.

Section III provides directions for proposal preparation.

Section IV of this announcement includes instructions for proposal submission (i.e., date, number of copies, where submitted) and general information on the USAMRMC's extramural research program and award administration.

Section V, the Appendices, is a summary of information, some of which must be included with the submitted proposal. All of the issues discussed in Appendices 1-7 must be addressed before an award can be made.

The DOD PCRP wants to ensure that all applicants' ideas are given fair consideration, and that the research that is ultimately funded best meets programmatic goals and is the finest of all proposals reviewed. Applicants should submit questions regarding this program in writing as early as possible. However, one should carefully review this announcement before submitting a question. The resources cited in this BAA as well as those available within local institutions (e.g., the Business or Contracts Office) should be fully utilized.

No extensions can be granted to the proposal submission deadlines. Every effort will be made to answer questions within ten working days of receipt. Inquiries must be restricted to format issues only; no questions relating to technical proposal content or reasonableness/allowableness of costs will be answered.

General information on the USAMRMC can be obtained on the World Wide Web at <http://mrmc-www.army.mil>. Specific information on the Congressional Special Interest Research Programs can be obtained at <http://mrmc-rad6.army.mil>. A copy of this BAA and associated forms (not including the proposal cover booklet) can be downloaded at <http://mrmc-rad6.army.mil/documents.html>.

Questions concerning the preparation of proposals, formats, or required documentation can be addressed to the USAMRMC at:

U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP-BAA-97)
524 Palacky Street
Fort Detrick, MD 21702-5024
Phone: (301)619-7079
Fax: (301)619-7792
E-mail: radvi_baa@ftdetrick-cmail.army.mil

Proposal Submission Requirements:

Proposal: one original and thirty copies.
Proposal Cover Booklet: one original and two copies.
Abstract Page: additional thirty copies in a manila envelope.
See unique requirements for specific award categories.

Proposal Submission Address:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP-BAA-97)
524 Palacky Street
Fort Detrick, MD 21702-5024

Proposal Deadline:

29 October 1997, 4:00 p.m. EST

U.S. ARMY 1997 PROSTATE CANCER RESEARCH PROGRAM PROPOSAL ACCEPTANCE CHECKLIST

Remember to Fax the Proposal Cover Booklet Order Form (blue in color).

The following criteria **MUST** be followed. Failure to conform to any of these criteria may lead to rejection of the proposal.

- ☐ Completed Proposal Cover Booklet/Bubble Sheet. You must submit an original booklet plus 2 copies. The following signatures are mandatory:
 - ☐ Principal Investigator
 - ☐ Institution Contracting Representatives
 - ☐ Official of the Institution (if applicable)
- ☐ Main Section: Maximum Page Limits
 - ☐ Proposal Title Page 1 Page
 - ☐ Table of Contents 1 Page
 - ☐ Proposal Abstracts (submitted on one page):
 - Technical Abstract ½ Page
 - Lay Abstract ½ Page
 - ☐ Proposal Relevance Statement 1 Page
 - ☐ Professional Experience and Preliminary Data (Idea Development Awards only) 1 Page
 - ☐ Proposal Body 6 Pages
 - ☐ Statement of Work 2 Pages
- ☐ Detailed Cost Estimate on standard budget form (see Appendix 1)

- ☐ Addenda
 - ☐ Addendum A - Acronym and Symbol Definition (1-page limit)
 - ☐ Addendum B - Illustrations/Diagrams/Chemical Syntheses (5-page limit)
 - ☐ Addendum C - Personnel Biographical Sketches (3-page limit per investigator)
 - ☐ Addendum D - Existing/Pending Support (no page limit)
 - ☐ Addendum E - References (no page limit; include full citation)
 - ☐ Addendum F - Publications and Patent Abstracts (up to 2 documents)
 - ☐ Addendum G - Facilities/Equipment Description (no page limit)
 - ☐ Addendum H - Statement of Eligibility (1-page limit; New Investigator Awards only)
- ☐ General Proposal Requirements:
 - ☐ Is every page single-spaced and single-sided? Double-sided pages may not be accepted (with the exception of article reprints).
 - ☐ Margins: Minimum of 0.5 inch top, bottom, right, and left
 - ☐ Paper Size: 8.5 inch x 11.0 inch
 - ☐ Type Font: 12 point throughout the proposal and addenda, except for Addendum F
- ☐ Submit the original proposal plus 30 copies.
 The original, including the addenda, must be collated and bound with a binder clip.
 Copies, including the addenda, must be collated and stapled. Do not use binder clips, rubber bands, or spiral or ring binders for copies.
 Do not pack copies of more than one proposal in the same box.
- ☐ Submit 30 additional copies of the abstract page in a manila envelope.
- ☐ For Idea Development proposals, submit 30 additional copies of the professional experience and preliminary data page in a manila envelope.
- ☐ Remember: The submission deadline is **29 October 1997 at 4:00 p.m. U.S. Eastern Standard Time**. You must allow time for the proposal to be delivered (see Section IV-B.5 for delivery details). **No exceptions will be made for late proposals.**

This checklist is for your use; it does not need to be submitted with the proposal.

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I. CATEGORIES OF AWARDS & FUNDING LEVELS



I. CATEGORIES OF AWARDS & FUNDING LEVELS

I-A. Overview of the Program

The United States Army Medical Research and Materiel Command (USAMRMC), through this Broad Agency Announcement (BAA), is soliciting applications for prostate cancer research. Proposals are sought across all areas of basic, clinical, behavioral, and epidemiological research. The objective of the USAMRMC Prostate Cancer Research Program (PCRP) is to promote innovative ideas that will lead to better understanding and control of prostate cancer. As directed in the Congressional language, the PCRP encourages innovative, multi-institutional, multi-disciplinary, and regionally focused research that is directed toward eliminating prostate cancer.

The USAMRMC is strongly encouraging the scientific community to undertake great strides in innovative research to conquer prostate cancer by calling for proposals that will foster new directions, breakthrough ideas, and approaches and will bring new investigators into the field of prostate cancer research. The central theme is innovation. Scientific ventures that represent under-investigated avenues of research or novel applications of existing technologies are highly sought. Proposals addressing the needs of minority, elderly, low-income, rural, and other under-represented populations are encouraged. Although the program wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

The programmatic strategy is being implemented by a solicitation for proposals in two research award categories: New Investigator Awards and Idea Development Awards. The intent of the New Investigator Award is to promote and reward innovative ideas and technology from new investigators to conquer prostate cancer. In accordance with this challenge to be innovative, the USAMRMC invites the submission of New Investigator proposals that may lack pilot data. The Idea Development Awards, on the other hand, are intended to support innovative projects from established investigators that **show promising preliminary data in prostate cancer**. The USAMRMC is particularly interested in preparing new scientists for careers in prostate cancer research and presenting an opportunity to move established investigators into the prostate cancer field.

The programmatic strategy features a change in emphasis from past Department of Defense (DOD) Congressional Special Interest Research Programs. The strategy is centered around a new **Dual-Phase Research Award**, as described in Section I-C. After two years of research, the USAMRMC will challenge all funded PCRP investigators to compete for an additional two years of funding. Awards will be given after a competitive evaluation to the prostate cancer investigators who (1) demonstrate the most productivity and innovation in Phase I and (2) submit the most scientifically promising Phase II research project.

Congress has appropriated \$38 M for the 1997 program, of which up to \$32 M is available for the Phase I Research Awards. Subject to the availability of funds in Fiscal Year (FY) 2000, the top Phase I investigators will be funded for two additional years. The research categories and the associated award mechanisms are described in Section I-C, followed by a description of who may apply and a call to reduce indirect costs.

All proposals in Phase I and Phase II will be evaluated in a two-tiered review process consisting of scientific merit review (peer review) in the first tier and programmatic relevance review in the second tier. Although scientific merit is an important criterion for award, proposals that receive high scientific merit scores in peer review but are judged to have low programmatic relevance are likely not to be selected for funding. Therefore, scientifically excellent studies that directly address the unique focus and goals of this program are most likely to receive funding support.

Prospective responders familiar with previous USAMRMC programs are urged to review this BAA carefully, as significant revisions in the award category definitions have been made.

I-B. Set-Aside for Historically Black Colleges and Universities/Minority Institutions

Up to 6 percent of the total funds allocated for the Prostate Cancer Research Program shall be for the exclusive participation by Historically Black Colleges and Universities/Minority Institutions (HBCU/MI), as defined by the Department of Education. Submissions are invited in both award categories. Similar to the overall program, the final investment strategy will be determined based on the quality and distribution of proposal submissions. To implement the set-aside program, proposals submitted from HBCU/MI will be reviewed collectively with all others in peer review but will be evaluated separately during programmatic review when award selections are determined.

I-C. Dual-Phase Research Awards

The vision of the Prostate Cancer Research Awards is qualitatively different from traditional awards. In an attempt to invigorate prostate cancer research, a new grant mechanism has been designed to specifically target innovative approaches, ideas, and investigators. Phase I of the **Dual-Phase** funding strategy is designed to support innovative ideas and approaches in prostate cancer research, while Phase II is designed to provide transition support to position investigators for competition in traditional funding mechanisms.

Applicants are required to include indirect costs according to the instructions listed in the Proposal Preparation section (Section III-B.3.i). The total dollar award will include the sum of the requested direct and indirect costs. **Budget remains a key consideration in both peer and**

programmatic review, and applicant's are cautioned to use discretion in budget requests (Sections I-E, II-D, and II-E).

I-C.1. Phase I

Allocation: Approximately \$32 M.

Approximately \$32 M will be allocated in Phase I to both the New Investigator and Idea Development Award Categories, as described in Sections I-C.1.a and I.C.1.b. Phase I awards will be funded over a thirty-month period. Investigators must include in the original submission a detailed description of the Phase I goals and Phase II experimental objectives. **Information must be included in the proposal that supports a scientifically sound research plan for Phase II.**

All of the Phase I awards must incorporate one of five designated research categories:

- Carcinogenesis, Etiology, and Tumor Biology
- Special Populations and Behavioral Patterns
- Genetics and Molecular Biology
- Prevention and Detection
- Therapeutics and Decreased Morbidity

Investigators may submit only one proposal and overlapping funded research is cause for administrative withdrawal prior to peer review. Investigators must self-declare a designated research category from the above list. Efforts will be made to fund a minimum of five proposals, inclusive of both the New Investigator and Idea Development Awards, in each of the designated research categories.

I-C.1.a. New Investigator Awards

Approximately \$4.2 M will be available to support the New Investigator Awards. New Investigator Awards will be for a maximum of \$75,000/year for thirty months (direct costs only) and may include up to \$1,500 annually for travel to scientific meetings. Cost reductions are considered in Sections I-E and III-B.3.j.

For the purpose of this award category, "New Investigator" is defined as an individual who fulfills **all** of the following criteria:

- (1) has their own independent research facilities;
- (2) is within six years of post-doctoral, residency, fellowship, or equivalent training; **and**,
- (3) holds a position as an Assistant Professor or equivalent.

New investigators competing for award must have a statement signed by the Dean of the Institution (or equivalent) indicating that they fulfill these eligibility criteria (see Section III.B.4.h).

The intent of the New Investigator Award category is to support innovative scientific approaches to prostate cancer research that may be untested but that are expected to reveal breakthroughs or new avenues of investigation. For the purpose of the PCRP, “innovative” is defined as:

- | | |
|---|--|
| * novel | * the start of something new |
| * looking at an existing problem from a new perspective | * creating or introducing something new or unusual |
| * challenging existing paradigms | * representing new paradigms |

Essential features of the New Investigator Awards are:

- This category seeks to reward new investigator submissions that undertake unattempted approaches to prostate cancer research.
- Although submissions may lack pilot data, the new investigator must nonetheless demonstrate solid scientific judgment and rationale.
- Applicants to the New Investigator Award category must describe in the Proposal Relevance Statement how the proposed work is truly innovative.
- The proposed funding will give new investigators the necessary support and time to determine whether an idea is worth pursuing and to gather the preliminary data needed to successfully compete in the future for a more traditional award.

FAILURE TO CONFORM TO THESE CRITERIA MAY LEAD TO REJECTION OF THE PROPOSAL.

I-C.1.b. Idea Development Awards

Approximately \$27.7 M will be available to support the Idea Development Awards. Awards will be for a maximum of \$125,000/year for thirty months (direct costs only) and may include up to \$1,500 annually for travel to scientific meetings. Cost reductions are considered in Sections I-E and III-B.3.j.

For the purpose of the Idea Development Awards, candidates must:

- (1) have some preliminary data in prostate cancer research relevant to the proposed project;
- (2) have their own independent research facilities; **and**,
- (3) hold a position of at least Assistant Professor level or equivalent.

The intent of the Idea Development Award is to give established prostate cancer investigators and those investigators who want to move into the prostate cancer field the necessary support and time to undertake under-investigated avenues of research. The USAMRMC will only consider proposals with preliminary data specifically in prostate cancer research. **All Idea Development investigators must submit with their proposals one page (total) that includes (1) promising, well-founded preliminary data in prostate cancer research that are relevant to the proposed project as well as (2) a summary of the principal investigators' research and professional experience in prostate cancer research and/or their potential for contribution in the prostate cancer field.**

The intent of the Idea Development Award category is to support innovative scientific approaches to prostate cancer research that although untested may reveal breakthroughs or new avenues of investigation. For the purpose of the PCRP, "innovative" is defined as:

- | | |
|---|--|
| * novel | * the start of something new |
| * looking at an existing problem from a new perspective | * creating or introducing something new or unusual |
| * challenging existing paradigms | * representing new paradigms |

FAILURE TO CONFORM TO THESE CRITERIA MAY LEAD TO REJECTION OF THE PROPOSAL.

I-C.2. Phase II

*Awards: New Investigator Awards will be for a maximum of \$150,000/year for two years.
Idea Development Awards will be for a maximum of \$250,000/year for two years.
Funding is contingent upon the availability of funds in FY 2000.*

After two years of research, the USAMRMC challenges all funded PCRP investigators (both New Investigators and Idea Development Investigators) from Phase I to compete for an additional two years of funding. Phase II awards are subject to the availability of funds in FY 2000.

To be eligible for Phase II funding, investigators funded in Phase I must submit progress reports in writing by 15 November 2000. Phase II awards will be made by April 2001 to those investigators who (1) demonstrate the most productivity and innovation in Phase I and (2) submit the most scientifically promising research project for Phase II. Only the best projects will be funded in Phase II, regardless of the investigator's designated research category.

I-D. Who May Apply

Eligible institutions include cooperative groups and for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, and agencies of local, State, and Federal governments. Foreign institutions are also eligible. Any individual, regardless of nationality or citizenship status, may apply as long as they are employed by an eligible institution. Investigators are cautioned that awards are made to institutions and that should a Principal Investigator (PI) move during the period of funding, transfer of funding is not assured. Sub-awards by the original recipient institution may be considered. Proposals are initiated by individuals but are formally submitted by their institutions.

The USAMRMC is especially interested in receiving applications from HBCU/MI. A set-aside is provided for these organizations as described in Section I-B.

I-E. Reducing Costs

In an effort to invigorate prostate cancer research, the USAMRMC requests that the investigator/institution award recipients cost-share in the research expenses. This request is being made due to the limited Congressional appropriation for prostate cancer research and the urgent need to maximize monies spent in the effort to conquer prostate cancer. Programmatic relevance and scientific and technical merit are the most important criteria; however, cost-sharing remains a key consideration and could be determinative in the event of equal programmatic relevance and scientific merit.

II. PROPOSAL EVALUATION



II. PROPOSAL EVALUATION

The USAMRMC utilizes a two-tiered review system for proposal evaluation involving separate phases for scientific merit review and programmatic review. The two tiers of review are fundamentally different. Scientific merit review is a criterion-based process in which individual proposals are evaluated for scientific and technical merit without regard to other proposals under consideration. In contrast, programmatic review is a comparison-based process in which proposals from multiple disciplines compete in a common pool. The evaluation of programmatic relevance during programmatic review involves direct comparisons of proposals that are judged to have high scientific merit in peer review. In order for a proposal to be funded, it must be recommended by both levels of the two-tiered review system.

II-A. Scientific Review Panels

Composition and responsibilities: The first level of review will be conducted by a multidisciplinary scientific peer review panel. The primary responsibility of the scientific peer review panel is to provide unbiased, expert advice to the USAMRMC on the scientific and technical merit of applications with respect to the review criteria articulated in the BAA. Given the expected complexity and multidisciplinary nature of proposals for this program, a multidisciplinary review panel will be constituted, as opposed to discipline-specific panels. The scientific review panel will include an executive secretary as a non-voting member, a chairperson, scientific reviewers across the full range of disciplines relevant to ovarian cancer, and two ovarian cancer consumer advocates as voting members. The scientific reviewers are recognized leaders in their fields and are chosen on the basis of relevant scientific expertise. Selection of the executive secretary and scientific reviewers is predicated upon their individual experience in scientific peer review. A list of all scientific panel members will be released after all awards are negotiated. However, to ensure the confidentiality of the review process, information regarding specific proposal assignments will not be released.

Consumer advocate panel members: Beginning with the FY 95 Breast Cancer Research Program, the USAMRMC has included survivors as consumer advocates in its science management activities to ensure the inclusion of their unique perspectives. Consumer advocates augment scientific merit review by broadening the perspective brought to the assessment of science. The FY 97 OCRP peer review will include consumers, defined as the prime beneficiaries of ovarian cancer prevention. Accordingly, consumer representatives may include survivors of the disease or women with a family history of ovarian cancer who have not been diagnosed with the disease.

Evaluation: Panel members will rate each proposal based on the specific evaluation criteria listed in Section II-C. Proposals will initially be assessed to determine whether the proposed work has substantial merit to warrant full review. All proposals that are determined to have insufficient scientific merit will be rejected without further review.

For proposals judged to have substantial merit, the scientific merit review process will involve two phases. First, each component project/core will be evaluated. Reviewers will rate the merit of each project using adjectival descriptors according to the scale that follows. Reviewers will have the discretion to reject individual projects/cores that are deemed to have insufficient merit for further consideration. Second, after all component projects and cores have been evaluated, reviewers will evaluate the overall effort. Rejected projects/cores will not be considered in the evaluation of the overall effort, but may nonetheless influence the rating of the overall effort inasmuch as the inclusion of poor quality projects represents a deficiency of judgment on the part of the Principal Investigator (PI).

Scoring Scale	
Outstanding	1.0-1.5
Excellent	1.5-2.0
Very Good	2.0-2.5
Good	2.5-3.5
Acceptable	3.5-5.0

Each evaluation criterion for the overall effort, with the exception of budget, will be rated on a scale of 1 (low merit) to 10 (high merit). Criteria scoring ensures that each component criterion is considered in the review. The criteria scores will not be averaged or manipulated to determine a priority score; instead, reviewers will use the criteria scores as a guide in determining a priority score. Once the overall effort has been reviewed, each reviewer will determine a priority score for the entire application using the scale listed above. The final priority score of the application will be the average of the individual reviewer scores.

II-B. The Integration Panel and Programmatic Review

Composition and responsibilities: Programmatic review will be conducted by an Integration Panel (IP). At the outset of the FY 93 Breast Cancer Research Program, the USAMRMC consulted the National Academy of Science's Institute of Medicine (IOM) for recommendations

II. PROPOSAL EVALUATION

The USAMRMC uses a two-tiered review system for proposal evaluation, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers of review are fundamentally different. The scientific merit review is a criterion-based process in which individual proposals are evaluated for scientific and technical merit. Programmatic review is a comparison-based process in which proposals from multiple disciplines compete in a common pool. By utilizing both levels of the two-tiered review system, the PCRP is able to fund a balanced research portfolio.

II-A. Scientific Review Panels

Composition and responsibilities: The first level of review will be conducted by scientific peer review panels organized by discipline or specialty areas. The primary responsibility of the scientific peer review panel is to provide unbiased, expert advice to the USAMRMC on the scientific and technical merit of applications with respect to the review criteria articulated in the BAA. Scientific review panels will include an executive secretary as a non-voting member and a chairperson, approximately 10-15 scientific reviewers, and two prostate cancer consumer advocates as voting members. The scientific reviewers are recognized leaders in their fields and are chosen on the basis of relevant scientific expertise. Selection of the executive secretaries and scientific reviewers is predicated upon their individual experience in scientific peer review. A list of all scientific panel members will be released after all awards are negotiated. However, to ensure the confidentiality of the scientific review process, information regarding specific panel and proposal assignments will not be released.

Consumer advocate panel members: The USAMRMC Breast Cancer Research Program (BCRP) implemented the recommendations of the Institute of Medicine for the BCRP by including breast cancer survivors as consumer advocates in its science management activities. Consumer advocates augment scientific merit review by broadening the perspective brought to the assessment of science. The FY 97 Prostate Cancer Research Program will continue in this tradition of consumer involvement.

Evaluation: Panel members will rate each proposal based on the specific evaluation criteria listed in Sections II-C and II-D. Two types of ratings are used: Each of the evaluation criteria, except for the budget, is rated on a scale of 1 (low merit) to 10 (high merit); and the overall proposal is given a global score using a scale of 5 (low merit) to 1 (high merit). Criteria scores are not averaged or manipulated to determine the global score. Instead, reviewers will use the criteria scores as a guide in determining a global score.

The USAMRMC peer review process has been designed to address concerns that New Investigator proposals that lack pilot data will not fare well in peer review. Orientations will be conducted for all peer reviewers, chairpersons, and executive secretaries so that they will recognize and reward proposals that meet the unique New Investigator criteria. In addition, New Investigator submissions will be evaluated separately to ensure full consideration of the unique New Investigator requirements.

II-B. The Integration Panel and Programmatic Review

Composition and responsibilities: The second level of review will be conducted by the PCRP Integration Panel (IP). At the outset of the FY 93 Breast Cancer Research Program, the USAMRMC consulted the National Academy of Science's Institute of Medicine for recommendations on program investment and management strategies. The Institute of Medicine made the following recommendation regarding the panel for the breast cancer program:

The committee recommends that the Army Medical R & D Command, as one of its first steps, appoint a council of 16 to 18 individuals that will advise the managers of the research program. The council's membership should represent multiple disciplines, including clinical, basic, and public health sciences, and also different geographic regions of the country; individuals should come from practice settings as well as academia and other research settings. The council should include qualified individuals at different career levels; most members should be experienced in biomedical review. Although the program will be housed in the Defense Department, the committee recommends that council members be primarily nonmilitary. Three or four members of the Advisory Council should represent consumer or public interests...The major tasks of the Advisory Council are to review the recommendations of the study sections, to make recommendations upon the final distribution of funds...

The PCRP Integration Panel for 1997 adheres to this guidance. The IP consists of a diverse group of basic and clinical scientists and consumers. The scientific members represent many diverse disciplines and specialty areas and are experienced with peer review procedures. In selecting the proposals which are recommended for funding, the IP not only bases decisions on scientific and technical merit but also considers such factors as the degree of innovative science, the relevance to the ultimate eradication of prostate cancer, and the potential for scientific breakthroughs. All submitted proposals undergo both scientific merit and programmatic review processes. Scientific merit review is criterion-based, while programmatic review is comparison-based. It is the responsibility of the IP to recommend a balanced portfolio of highly meritorious science that meets the programmatic objectives of innovation and scientific diversity.

Consumer advocate panel members: Consumer advocates participate in all phases of PCRP Integration Panel deliberations. With their first-hand experience, consumer advocates have the capacity to enhance the review process by focusing attention upon critical patient issues and outcomes. Most consumer advocates represent nationally known advocacy groups that have been instrumental in raising public awareness and interest in supporting prostate cancer research.

Evaluation: The IP reviews the results of the scientific review panels' deliberations and makes recommendations on the final distribution of funds by matching scientific excellence with the programmatic objectives. *Note that a major programmatic objective and evaluation criterion is to reduce costs by encouraging the investigator/institution award recipients to cost-share in the research expenses.* Final funding recommendations are forwarded to the Commanding General of the USAMRMC for approval.

II-C. Screening Idea Development Awards

The intent of the Idea Development Award is to give established prostate cancer investigators and those investigators who want to move into the prostate cancer field the necessary support and time to undertake under-investigated avenues of research. All Idea Development Awards will be administratively screened prior to scientific peer review to verify that (1) the preliminary data were obtained in prostate cancer research and (2) the investigator is dedicated to prostate cancer research. **Idea Development proposals lacking promising data in prostate cancer research are not permitted.** New Investigator proposals are not subject to administrative screening.

II-D. Scientific Peer Review Evaluation Criteria for Research Awards

II-D.1. New Investigator Awards

All New Investigator proposals will be evaluated according to the criteria listed below:

- a. Originality and innovative nature of proposal
- b. Hypothesis, rationale, and research strategy
- c. Scientific relevance (defined as the relevance of the proposal to a critical problem in prostate cancer research and how significantly it will advance that field)

- d. Qualifications of the Principal Investigator and staff
- e. Adequacy of resources and environment to support the project

II-D.2. Idea Development Awards

All Idea Development proposals will be evaluated according to the criteria listed below:

- a. Originality and innovative nature of proposal
- b. Hypothesis, rationale, and research strategy
- c. Scientific relevance (defined as the relevance of the proposal to a critical problem in prostate cancer research and how significantly it will advance that field)
- d. Feasibility and promise of approaches as predicted by the preliminary data
- e. Qualifications of the Principal Investigator and staff
- f. Adequacy of resources and environment to support the project

II-E. Programmatic Review Process Description

Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. Programmatic relevance is an assessment that balances the risks and potential outcomes of scientifically excellent proposals to best fulfill the PCRP goals and objectives. The IP does not automatically recommend funding for all highly scored proposals reviewed by scientific peer review panels, nor does it re-review the scientific and technical merit. Instead, it carefully scrutinizes each proposal in an attempt to allocate, as wisely as possible, the funds available for each award mechanism. Features that the IP uses to make funding recommendations are:

- a. Ratings and recommendations of the peer review panels
- b. Programmatic relevance
- c. Budget appropriateness (including cost-sharing)
- d. Program portfolio balance with respect to research disciplines
- e. Other factors such as adequate support for new investigators and appropriate gender, minority, and geographic distribution
- f. Research targeting minority populations

Cost-sharing by the investigator/institution will be a key consideration in programmatic review. While final program authority rests with the Commanding General of the USAMRMC, due consideration will be given to the recommendations provided by the IP.

II-F. Award Notification

Following completion of the two-tiered evaluation process, all principal investigators who submit compliant proposals will receive a letter indicating their funding status, along with a scientific review summary critique of their proposal. Scientific review summaries will contain the proposal global score and the individual evaluation criteria scores, along with detailed comments that provide a summary review and address the proposal's strengths and weaknesses with respect to each evaluation criterion. It is expected that this information will be distributed in May 1998. All award negotiations for Phase I will be completed by 30 September 1998.

III. PROPOSAL PREPARATION



III. PROPOSAL PREPARATION

III-A. General Information

III-A.1. Proposal Requirements

Proposals submitted in response to this Broad Agency Announcement must conform to the order, length, and format requirements described in this section. Proposals that exceed the page limitations, do not include an original Proposal Cover Booklet, and/or do not contain the prescribed contents and signatures **MAY NOT RECEIVE FURTHER CONSIDERATION**. Proposals that are received late **WILL NOT RECEIVE FURTHER CONSIDERATION**.

- Proposals shall contain five principal parts:
 1. proposal cover booklet (bubble sheet)
 2. main section
 3. detailed cost estimate
 4. addenda
 5. appendices (to be submitted upon request after peer review)
- Length requirements are indicated in the Proposal Contents (see Section III-A.2).
- All parts of the proposal, with the exception of the proposal cover booklet, publications, and patent abstracts, will:
 1. be single-spaced, single-sided
 2. have margins no less than 0.5 inches on all sides
 3. have font no smaller than 12 point
 4. be submitted in English
 5. be on 8.5" x 11" paper (**Note to International applicants: A4 paper will be accepted if the text of the proposal does not exceed 7.5" x 10".**)
- *Use the following lines as an example for spacing, font, and margins. If font size is smaller (less than 12 point) or margins are narrower (less than 0.5 inches), then the proposal will be administratively rejected.*

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. 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.

- Use the Proposal Acceptance Checklist (pages iii-iv) to verify that all proposal acceptance criteria have been met, but do not submit this checklist with the proposal.

Duplicate/Multiple Submissions: Duplicate submissions of the same research project under different award mechanisms will not be accepted. *Only one application per investigator is allowed.* Funding for overlapping research is cause for administrative withdrawal prior to peer review.

USAMRMC Policy for the Inclusion of Women and Minorities in Clinical Studies: Women and minorities must be included in all *appropriate* USAMRMC-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This information should be included in human use documentation, as described in Appendix 5 of this BAA. Please note, however, that the human use documentation is not to be submitted with the proposal but must be immediately available upon USAMRMC request (approximately February 1998).

III-A.2. Proposal Contents

Five principal parts are required and should be included in the following order:

Part 1. Proposal Cover Booklet

Ordering Proposal Cover Booklets: Cover booklets can be obtained by completing the **Blue Order Form for Proposal Cover Booklet** and faxing it to (301)682-5521. On the form include a brief description of the proposed research. Once this form is received, you will be sent two original Proposal Cover Booklets. Proposals will not be accepted without an original and two copies of the Proposal Cover Booklet. *Note: If you do not receive your booklets within ten working days of request, re-order by calling (301)682-5501.*

See Section III-B.1 for specific instructions for completion of the Proposal Cover Booklet.

Part 2. Main Section

New Investigator proposals (Main Section is not to exceed 12 pages)

A.	Proposal Title Page	page 1
B.	Table of Contents	page 2
C.	Proposal Abstracts (Technical and Lay)	page 3
D.	Proposal Relevance Statement	page 4

- | | | |
|----|-------------------|-------------|
| E. | Proposal Body | pages 5-10 |
| F. | Statement of Work | pages 11-12 |

Idea Development proposals (Main Section is not to exceed 13 pages)

- | | | |
|----|--|-------------|
| A. | Proposal Title Page | page 1 |
| B. | Table of Contents | page 2 |
| C. | Proposal Abstracts (Technical and Lay) | page 3 |
| D. | Proposal Relevance Statement | page 4 |
| E. | Professional Experience and Preliminary Data | page 5 |
| F. | Proposal Body | pages 6-11 |
| G. | Statement of Work | pages 12-13 |

Part 3. Detailed Cost Estimate (no page limit)

Instructions for completing the cost estimate can be found in Section III-B.3. This detailed cost estimate must be completed on the form provided in Appendix 1 of this BAA.

- A. Personnel Costs
- B. Consultant Costs
- C. Major Equipment
- D. Materials, Supplies, and Consumables
- E. Travel Costs
- F. Research-Related Patient Costs
- G. Other Expenses
- H. Consortium Costs
- I. Indirect Costs
- J. Cost-Sharing

Part 4. Addenda

For specific instructions on completing the addenda, see Section III-B.4. **Proposals that fail to adhere to specified page limits, are incomplete, and/or contain unrequested material may be rejected.** Therefore, include only the following addenda:

- A. Acronym and Symbol Definition (1-page limit)
- B. Illustrations/Diagrams/Chemical Syntheses (5-page limit)
- C. Personnel Biographical Sketches (3-page limit per investigator)
- D. Existing/Pending Support (no page limit)
- E. References (no page limit; include full citation)
- F. Publications and Patent Abstracts (up to 2 documents)
- G. Facilities/Equipment Description (no page limit)
- H. Statement of Eligibility (1-page limit; New Investigator Awards only)

Part 5. Appendices (no page limit)

The following appendices must be prepared where appropriate. They are NOT to be included with the initial submission but must be immediately available upon USAMRMC request on or about 1 February 1998. **Failure to respond may result in an award not being made.** A complete proposal title page (see Section III-B.2.a for instructions) must accompany these appendices.

- A. Regulatory Compliance Checklist/Form (use form in Appendix 3 of this BAA)
- B. Certificate of Environmental Compliance (use form in Appendix 4 of this BAA)
- C. Research Involving Human Subjects and/or Human Anatomical Substances (see Appendix 5 of this BAA)
- D. Research Involving Animals (see Appendix 6 of this BAA)
- E. Safety Program Plan (see Appendix 7 of this BAA)

III-B. Specific Instructions

III-B.1. Proposal Cover Booklet (Bubble Sheet)

Ordering the Proposal Cover Booklet (Bubble Sheet)

You must submit an original Proposal Cover Booklet and two copies. Two booklets will be forwarded to all investigators who fax in a Blue Order Form for Proposal Cover Booklet. The Proposal Cover Booklet must be filled out carefully to ensure that each proposal is assigned to the appropriate review panel. In the event that additional booklets are needed, investigators may request these by:

Fax: (301)682-5521

Phone: (301)682-5501

E-mail: radvi_baa@ftdetrck-ccmail.army.mil

Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF PCRP-BAA-97
524 Palacky Street
Fort Detrick, MD 21702-5024

Allow sufficient time for delivery by regular mail.

ATTENTION: In order to facilitate the processing of the proposal, it is extremely important that you *read and follow the instructions completely* as you are filling out the Proposal Cover Booklet. Verify that the written and bubbled figures match exactly.

Completing the Proposal Cover Booklet (Bubble Sheet)

1. **Proposal Log Number.** (Official Use Only). Leave blank.
2. **BAA Identifier.** Fill out with "PCRP-97," submission award category, and designated research category as listed below (example: PCRP-97, New Investigator, Prevention and Detection):

AWARD CATEGORY

New Investigator
Idea Development

DESIGNATED RESEARCH CATEGORY

Carcinogenesis, Etiology, and Tumor Biology
Special Populations and Behavioral Patterns
Genetics and Molecular Biology
Prevention and Detection
Therapeutics and Decreased Morbidity

3. **Organization Code.** (Official Use Only). Leave blank.
4. **Organization Name and Address.** Indicate the name and address of the organization that is submitting the proposal on the PI's behalf. This is the address for the **Contracting/Business Office** of the PI's organization. It is the address for the administrative official indicated in Question 36 who is authorized to conduct negotiations on the applicant's behalf.
5. **Type of Organization.** Choose one primary type and all applicable subtypes within that primary subtype from the list provided in the Proposal Cover Booklet. Refer to the proper Government document to determine HBCU/MI status (see also Section IV-A.2).
6. **Principal Investigator Last Name, First Name, and Middle Initial.** The PI is the individual who is primarily responsible for the proposed research.
7. **Title.** Indicate the appropriate title for the PI.
8. **Rank.** Federal employees must fill out their rank completely. If the PI is not a Federal employee, leave this blank.
- 9-15. **Principal Investigator's Mailing Address.** Fill out the PI's correct mailing address. This is the address where the work will be performed. **Do not use the PI's home address.** If applicable, state the PI's organization and department, then street address. Do not use abbreviations or acronyms of any kind in the address. Do not use formal terms such as "The" or "The Trustees of" when indicating the organization. Where no organization or department name is necessary, fill out the applicant's street address only. If possible, avoid the use of PO Boxes. International applicants should use the appropriate country code (see Appendix 9 of this BAA) for question 14. Also, write in any international numeric postal code in the space indicated under question 15.

- 16-17. **Principal Investigator's Phone and Fax numbers.** U.S. and Canadian phone numbers must be filled in completely. If the PI has international phone and fax numbers, indicate them, including the city code and country code, in the spaces provided.
18. **Principal Investigator's E-mail Address.** If the PI has access to e-mail, write the address in the space provided.
19. **Demographics.** (Optional). Indicate the PI's gender and ethnicity, if desired.
20. **Degree.** Indicate all that apply.
21. **Proposal Title.** Enter the title of the proposal. This may be up to 160 characters long. Capitalize the initial word and the first letter of each subsequent word, with the exception of prepositions and articles. Please note that each blank space is equivalent to one character.
22. **Total Funding Requested.** Fill in the total dollar amount requested. This is the total dollar amount for all direct and indirect costs for the entire period of the Phase I research as indicated in the Budget Section of the proposal. Enter amounts in whole U.S. dollar figures only. **Please be sure to include only the costs requested from the Government. Do NOT** include in this figure the amount the institution is willing to cost-share. Record dollar amounts in the right-hand column; any blank spaces should be to the left of the amount.
23. **Military/Civilian Collaboration.** Indicate whether the proposal DOES or DOES NOT involve a military/civilian collaboration. If the proposal DOES represent a military/civilian collaboration, fill in the full name and address of the collaborating organization. Note that the lead partner is the non-DOD organization. Therefore, the military organization should be listed here as the collaborating organization.
24. **Human Subjects and Anatomical Specimens.** (Official Use Only). Leave blank.
25. **Number of Human Subjects.** (Official Use Only). Leave blank.
26. **Animal Subjects.** (Official Use Only). Leave blank.
27. **Number of Animal Subjects.** (Official Use Only). Leave blank.
28. **Safety Provisions.** (Official Use Only). Leave blank.
29. **Proposal Category.** Select the ONE code from the following list that applies to the proposal and enter it in the space provided. **This MUST be filled out with careful consideration, because it will determine, in part, how the proposal will be assigned and evaluated for funding.**

TYPE OF AWARD**CODE**

New Investigator Awards

10

Idea Development Awards

20

30. **Mentor Name.** (Official Use Only). Leave blank.

31. **Research Classification.** From the following list, choose the ONE research classification code that best describes the proposed research.

CLASSIFICATION**CODE**

Basic Research

10

Clinical Research

20

Behavioral/Psychosocial Research

30

Epidemiology/Public Health Research

40

Clinical Trials

50

32. **Primary Research Area.** From the "Research Area" list that follows, select ONE Primary Research Area code that best describes the proposed research.

RESEARCH AREA**CODE**

Special Populations and Behavioral Patterns

100

Prevention and Detection

101

Carcinogenesis, Etiology, and Tumor Biology

102

Therapeutics and Decreased Morbidity

103

Genetics and Molecular Biology

104

33. **Secondary Research Area.** (Official Use Only). Leave blank.

34. *If the proposed research involves human subjects, answer questions 34 & 35.* Does the proposed research target one or more of the following minority populations: African-American, Asian, Hispanic/Latino, Native American, or Pacific Islander?

Please use the following codes to answer this question:

- If the proposed effort **does target minority populations**, use code 100.
- If the proposed effort **does not target minority populations**, use code 200.

35. Does the project have a **planned outreach effort** to recruit and retain minority populations in the study? The goal is to develop appropriate lines of communication and to build mutual trust so that both the study and minority communities benefit from the collaboration.

Please use the following codes to answer this question:

- If the proposed effort **has** such a plan, use code 100.
- If the proposed effort **does not have** such a plan, use code 200.

36. **Administrative Representative Authorized to Conduct Negotiations.** Indicate the primary and secondary administrative contacts authorized to conduct negotiations on the investigator's behalf. The address for the primary contact must be indicated in question 4 on the first page of the Proposal Cover Booklet. If the organization has a Contracting/Business Official, this is the authorized individual contacted to negotiate potential awards. The signature of the institutional representative certifies that the offeror (sponsoring institution) has examined the investigator's credentials and verifies that the investigator is qualified to conduct the proposed study and to use humans and/or animals as research subjects (if appropriate). **THIS SIGNATURE IS MANDATORY.** Failure to obtain this signature may result in the rejection of the proposal.
37. **Official of the Institution.** In cases where the individual in question 36 is not officially authorized to offer the proposal, this signature is mandatory. Please obtain the appropriate certifying signature in this block.
38. **Principal Investigator.** The PI must sign in the space indicated. **THIS SIGNATURE IS MANDATORY.**

Check this cover booklet carefully for mistakes before sending it with the proposal. Mistakes in this booklet may result in misassignment of the proposal to an inappropriate scientific merit review panel or rejection of your submission. If you have any questions about the PCRP, the BAA, or the Proposal Cover Booklet, please e-mail: radvi_baa@ftdetrck-ccmail.army.mil, or call: (301)619-7079.

III-B.2. Main Section

An original plus 30 collated copies of the proposal are required. The proposal original should be marked "Original" in the upper right corner. The original copy should not be stapled but should be bound with binder clips. The additional 30 copies must be stapled.

III-B.2.a. Proposal Title Page - 1-page limit (font and margin requirements apply)

A Proposal Title Page must accompany every proposal submission and must include the following information:

1. Proposal Title
2. Award Category

3. Organization Name and Location to include city, state, and country (if non-U.S.)
4. Principal Investigator's Phone and Fax Numbers
5. Principal Investigator's Full Name, including middle initial
6. Contracting Representative's Name
7. Contracting Representative's Phone and Fax Numbers

III-B.2.b. Table of Contents - 1-page limit (font and margin requirements apply)

Prepare a Table of Contents, with page numbers, following the outline presented in Section III-A.2, part 2 through part 4. Number all pages consecutively at the bottom, beginning with the Proposal Title Page, throughout the entire application.

III-B.2.c. Proposal Abstract Page - 1-page limit (font and margin requirements apply)

Two abstracts are required: One technical abstract and one lay abstract. One goal of the PCRP is to increase the education of the lay community. Therefore, an abstract targeted to non-scientists must be included. Each abstract must not exceed ½ page in length, and both must be printed on the same page.

The proposal abstract page, containing the technical and lay abstracts, must precede the body of the proposal. The abstract page is distinct from, and will not be counted among, the page limits imposed upon the proposal body.

In addition to the abstract page contained within the proposal, submit 30 copies of the abstract page in a manila envelope. Note that abstracts of all funded proposals will be reproduced in a PCRP abstract book and posted on the Internet.

The abstract page shall contain the following items:

1. Title of the Proposal
2. PI Name
3. Up to Five Key Words Relevant to the Proposal
4. Abstracts (Technical and Lay)

III-B.2.d. Proposal Relevance Statement - 1-page limit (font and margin requirements apply)

A Proposal Relevance Statement, not to exceed one page, must precede the body of the proposal. The Proposal Relevance Statement is distinct from, and will not be counted among, the page limits imposed upon the proposal body. The investigator should make a case that the proposed

research is relevant to one or more critical issues in prostate cancer research. State explicitly how the proposed work is innovative. Articulate how the combination of innovation and relevance in the proposal will have an impact upon and further the programmatic goals.

III-B.2.e. Professional Experience and Preliminary Data (Idea Development Investigators Only) - 1-page limit (font and margin requirements apply)

A succinct summary of the investigator's professional experience in prostate cancer research and preliminary data in prostate cancer research must precede the body of the proposal. All Idea Development Investigators must submit a summary of promising and well-founded preliminary data in prostate cancer research that is relevant to the proposed project, as well as a summary of their research and professional experience in prostate cancer research and/or their potential for contribution to the prostate cancer field. **During the screening process, all Idea Development proposals will be administratively reviewed to verify that the data are directly derived from prostate cancer research.**

NOTE: Tables, figure legends, and captions included on this page must conform to font and margin requirements.

In addition to the professional experience/preliminary data page contained within the proposal, submit 30 additional copies of this page in a separate manila envelope.

III-B.2.f. Proposal Body - 6-page limit (font and margin requirements apply)

A concise description of the research to be undertaken shall be submitted. The following general outline should be followed: background, hypothesis/purpose, technical objective, and methods. Evaluation of the proposed research will be influenced by the quality of this information. Please note that only New Investigator submissions do not require preliminary data. **The proposal body must not exceed six pages in length.**

NOTE: Tables, figure legends, and captions must conform to font and margin requirements.

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

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

Technical Objectives: State concisely the specific aims of the study.

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. If necessary, these diagrams may be placed in Addendum B. **Use of Addenda to continue providing specific written details of the experimental design or methodology may result in rejection of the proposal.**

The theme of innovation should be integrated throughout the body of the proposal.

III-B.2.g. Statement of Work - 2-page limit (font and margin requirements apply)

The Statement of Work is a concise restatement of the research proposal that outlines and establishes the PI performance expectations for which the USAMRMC will provide 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.

Every proposal submitted in response to this BAA must contain a Statement of Work, in outline form, prepared by the proposer. A series of relatively short statements should be included that comprise the stepwise approach to each of the major goals or objectives of the proposed research. As appropriate, the Statement of Work should:

- describe work to be accomplished as tasks.
- identify the timeline and milestones for the work over the period of the proposed effort.
- indicate the numbers of research subjects (animal or human) for each task.
- identify methods. (Do not describe in detail.)
- identify products/deliverables for each phase of the project.

As a guide, the Statement of Work for a 30-month effort should require approximately one page of single-spaced typing. Several sample Statements of Work are included as Appendix 8 of this BAA.

III-B.3. Detailed Cost Estimate - Must use form contained in Appendix 1 of this BAA.

In an effort to invigorate prostate cancer research, the USAMRMC is forced to request that the investigator/institution award recipients cost-share in the research. This request is being made due to the limited Congressional appropriation for prostate cancer research and the urgent need to maximize monies spent in the effort to conquer prostate cancer. **Institutions unable to cost-share are discouraged from applying.**

The USAMRMC has introduced a standard budget form to assist in the preparation of detailed cost estimates and to facilitate the review of budgets during proposal evaluation. This form, included as Appendix 1 of this BAA, is the only form that should be used for preparing cost estimates. **Please be advised that submissions containing budget forms other than the USAMRMC standard form may not receive further consideration.**

Each item in the budget must be clearly justified on the *Justification* page (page 3 of the budget form). Further, itemize all budget categories for additional years of support on the *Justification* page. All amounts must be in U.S. dollars. For projects with a substantial foreign component, explain and justify this on the *Justification* page.

An estimate of the total research project cost, with a breakdown of direct and indirect costs by category and year, must accompany each formal proposal. Costs for multiple-year proposals should cover the total estimated duration of the project. Costs proposed must conform with the following regulations and principles:

Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, Contract Cost Principles and Procedures.

Educational Institutions: OMB Circular A-21, Cost Principles for Educational Institutions.

Nonprofit Organizations: OMB Circular A-122, Cost Principles for Nonprofit Organizations.

OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.

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

It is the policy of the DOD that awards are made to institutions and that should a PI move during the period of funding, transfer of funding is not assured. Sub-awards by the original recipient institution may be considered.

III-B.3.a. Personnel Costs

Show projected salary amounts in terms of annual salary and percent effort on the project to be charged by the Principal Investigator(s), research associates, and assistants and the total amount

per year to be paid to each staff member of the project. Starting with the Principal Investigator, list the names of all employees of the applicant who are 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.

The qualifications of the PI and the amount of time that he/she and other senior professional key personnel will devote to the research are important factors affecting the selection of research proposals. 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.

Role on Project: Identify the role of each individual listed on the project. Describe their specific functions on the *Justification* page (page 3 of the budget form).

Type of Appointment/Months: List the number of months per year reflected in an individual's contractual appointment to 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, identify this with an asterisk (*) and provide a full explanation on the *Justification* page (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.

Percent of Effort on Project: For each key staff member identified on the budget form, list the percent of each appointment to be spent on this project.

Salary Requested: Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percent 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.

III-B.3.b. Consultant Costs

Whether costs are/are not involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium arrangements.

III-B.3.c. Major Equipment

It is the policy of the Department of Defense 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.

III-B.3.d. Materials, Supplies, and Consumables

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

III-B.3.e. Travel Costs

List the number of trips, destinations, and purposes for all proposed travel. Estimate round-trip 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 on the *Justification* page (page 3 of the budget form).

III-B.3.f. 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.

III-B.3.g. Other Expenses

Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (giving hours and rates), communication costs, etc. 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.

III-B.3.h. 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 (cost reimbursement, fixed price, etc.);
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.

III-B.3.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 must be disclosed and a statement to identify whether the proposed rates are provisional or fixed. A copy of the negotiation memorandum should be provided. If negotiated forecast rates do not exist, sufficient detail must be provided to enable a determination that the costs included in the forecast rate are allocable. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how they were established. As a minimum, submissions should identify:

1. all individual cost elements included in the forecast rate(s);
2. the basis used to prorate indirect expenses to cost pools, if any;
3. how the rate(s) were calculated; and
4. the distribution basis of the developed rate(s).

III-B.3.j. Cost-Sharing

Detail in the space provided the projected cost-share totals by the institution and Government. Itemize individual cost-share items for the entire project. Examples of expenses that may be cost-shared include any of the following: personnel, consultant, equipment, materials, supplies, consumables, travel, research-related, and any other expenses.

III-B.3.k. 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 on the *Justification* page. Identify 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.

III-B.4. Addenda

Include only items appropriate to the proposal. Note the page limitations that apply to each addendum. All formatting requirements are enforced in the Addenda, excluding Addendum F. Use of addenda to continue providing specific written details of the experimental design or methodology may result in rejection of the proposal.

III-B.4.a. Acronym and Symbol Definition - 1-page limit (font and margin requirements apply)

Provide a glossary of all acronyms and symbols.

III-B.4.b. Illustrations/Diagrams/Chemical Syntheses - 5-page limit (font and margin requirements apply)

Note: Tables, figure legends, and captions must conform to font and margin requirements.

ONLY figures, tables, diagrams, and chemical syntheses *with minimal figure legends* may be included in this addendum.

III-B.4.c. Personnel Biographical Sketches - 3-page limit per investigator (font and margin requirements apply--Use the form provided as Appendix 2 of this BAA.)

Biographical sketches should be prepared for each of the key personnel listed on the budget page for the initial budget period and must not exceed three pages per investigator. Use the form "Biographical Sketches" provided as Appendix 2 of this BAA. A list of significant publications should be incorporated into the biographical sketch. Curricula vitae that exceed this limit must not be included.

III-B.4.d. Existing/Pending Support - no page limit (font and margin requirements apply)

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 must not duplicate other funded research projects.

III-B.4.e. References - no page limit; must include full citation (font and margin requirements apply)

List the references in the order they appear in the proposal narrative. Use a reference format that gives the title of the citation.

III-B.4.f. Publications and Patent Abstracts - 2-document limit

You may include relevant publication reprints and patent abstracts, up to two documents.

III-B.4.g. Facilities/Equipment Description - no page limit (font and margin requirements apply)

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

III-B.4.h. Statement of Eligibility for New Investigators - 1-page limit (font and margin requirements apply)

The USAMRMC is interested in preparing new investigators for careers in prostate cancer research. It is, therefore, required that all new investigators submit a statement signed by the Dean of the Institution (or equivalent) attesting that the investigator:

1. has their own independent research facilities;
2. is within six years of post-doctoral, residency, fellowship, or equivalent training; and
3. holds a position as an Assistant Professor or equivalent.

III-B.5. Appendices

The appendices for Regulatory Compliance, Environmental Compliance, Human Use, Animal Use, and Safety Plan must be prepared where appropriate. They are not to be included with the initial submission but **must be immediately available upon USAMRMC's request on or about 1 February 1998. Failure to respond may prevent further consideration of the proposal.**

A completed proposal title page should accompany these supplements. The forms required to complete these appendices can be downloaded from the following World Wide Web site:

<http://mrmc-rad6.army.mil/documents.html>

III-B.5.a. Regulatory Compliance Checklist/Form

Appendix 3 must be completed and forwarded when supplements are requested.

III-B.5.b. Certificate of Environmental Compliance

The Certificate, found in Appendix 4 of this BAA, must be executed by the institution's official responsible for environmental compliance.

Potential Requirement for Environmental Impact Data

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 U.S., for their potential environmental impacts. In most cases, contractors conducting research in established laboratories that are in compliance with environmental laws and

regulations, or 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 Army regulations (AR 200-2) that implement the CEQ regulations.

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 DNA molecules into the genome of one or more human subjects, requires BSL3 or BSL4 safety levels, or uses animals captured from the wild), further information may be requested to allow a determination of the environmental impact of the proposed research to be made. You must submit this information in a timely manner in order to receive an award.

III-B.5.c. Research Involving Human Subjects and/or Human Anatomical Substances

Address all pertinent issues relating to the use of human subjects and anatomical substances in the proposed research. Include the required approvals, forms, and descriptions as outlined in Appendix 5 of this BAA.

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

III-B.5.d. Research Involving Animals

Address all pertinent issues relating to the use of animals in the proposed research. Include the required assurances, approvals, forms, and descriptions as outlined in Appendix 6 of this BAA. (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.)

Note that Department of Defense procedures for reviewing and approving the use of animals in research differ from those required by other funding agencies.

III-B.5.e. Safety Program Plan

Address all pertinent issues and include the required assurances, approvals, forms, and descriptions relating to safety as outlined in Appendix 7 of this BAA.

IV. GENERAL INFORMATION



IV. GENERAL INFORMATION

IV-A. Policy and Procedures

IV-A.1. 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 U.S. Army Medical Research Acquisition Activity (USAMRAA).

All awards are made to organizations, not individuals. A Principal Investigator must submit a proposal through, and be employed by, a university, college, nonprofit research institute, commercial firm, or Government agency in order to receive support.

IV-A.2. Historically Black Colleges and Universities/Minority Institutions

Set-aside funding for Historically Black Colleges and Universities and Minority Institutions for the components of this program is described in Section I-B of this BAA.

Historically Black Colleges and Universities are institutions determined by the Secretary of Education to meet the requirements of 34 CFR Subpart 608.2.

Minority Institutions are institutions determined by the Secretary of Education to meet the requirements of 34 CFR Subpart 607.2. The term also includes any nonprofit research institution that was an integral part of a Historically Black College or University before 14 November 1986.

IV-A.3. 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.

IV-B. Proposal

IV-B.1. 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 will 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.

IV-B.2. Award Eligibility

To be eligible for award, a prospective recipient must 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).

IV-B.3. Government Obligation

PIs are cautioned that only an appointed Contracting 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 technical discussions with a technical project officer. A PI 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 Officer does so at his/her own risk.

IV-B.4. 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.

IV-B.5. Proposal Submission Deadline

The submission deadline for all component projects solicited in this BAA is 29 October 1997 and will be strictly enforced.

All submissions must be received at the address listed in Section IV-B.6 no later than 4:00 p.m. Eastern Standard Time on 29 October 1997. Any proposal received after the exact time specified for receipt will 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.
2. was sent by U.S. Postal Service Express Mail Next Day Delivery--Post Office to Addressee and postmarked no later than 5:00 p.m. on 28 October 1997.
3. was sent by other commercial overnight courier service and placed into their control no later than 5:00 p.m. on 28 October 1997.

Reminder: This specification is for all submissions.

IV-B.6. Proposal Copies/Submission Address

Thirty-one copies, including one original, will be submitted to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP BAA 97)
524 Palacky Street
Fort Detrick, MD 21702-5024

Refer to Section III, Proposal Preparation, and the appendices cited therein to ensure that all items have been addressed or completed.

If the applicant wants an acknowledgment of proposal receipt, enclose a self-addressed, stamped postcard with the proposal. The postcard should state the proposal title.

IV-B.7. Funding Instrument

The funding instrument for all awards to academic and nonprofit institutions under this BAA will be grants. Cooperative agreements may be used where appropriate.

More information on these funding instruments may be obtained on request from:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA
Fort Detrick, MD 21702-5014
Fax: (301)619-2937

IV-C. Research Administration

IV-C.1. Deliverables

The grant or cooperative agreement will require the timely delivery of several reports during the research effort. The Recipient and the Principal Investigator must realize that reports are necessary for the USAMRMC to monitor progress. While a particular research project may call for some variation, the PI should plan on a requirement that consists of:

- a. an ANNUAL report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and
- b. a FINAL report (submitted in the last year of the grant period) that details the findings and issues of the entire project.

A copy of the manuscript or subsequent reprints of any publications resulting from the research **must** be submitted to the USAMRMC.

IV-C.2. Equipment/Property

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 in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

Commercial organizations, including nonprofit institutions, are expected to possess the necessary facilities and equipment to conduct the proposed research. Generally, no funds will be authorized for equipment acquisition.

IV-D. Other Publications

Investigators are strongly encouraged to publish their results in scientific literature. A copy of the manuscripts or subsequent reprints of any publications resulting from the research **must** be submitted to the USAMRMC.

V. APPENDICES



Appendix 1 Detailed Cost Estimate

Principal Investigator (*last, first, middle*)

DETAILED BUDGET FOR INITIAL BUDGET PERIOD					FROM	THROUGH	
PERSONNEL (APPLICANT ORGANIZATION ONLY)		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						
Personnel Direct Costs Subtotals →→→→→→→→→→							\$
CONSULTANT COST							
EQUIPMENT (ITEMIZE)							
SUPPLIES (ITEMIZE BY CATEGORY)							
TRAVEL							
RESEARCH-RELATED PATIENT COST							
OTHER EXPENSES (ITEMIZE BY CATEGORY)							
CONSORTIUM COSTS		DIRECT					
		INDIRECT					
SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD →→→→→→→→→→							\$
TOTAL PERSONNEL & OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD							\$
TOTAL COSTS FOR INITIAL BUDGET PERIOD							\$
INSTITUTIONAL COST SHARE							\$
GOVERNMENT COST SHARE							\$

Principal Investigator (last, first, middle)

BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT						
BUDGET CATEGORY TOTALS*		INITIAL BUDGET PERIOD (FROM FORM PAGE 1)	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL						
FRINGE BENEFITS						
CONSULTANT COST						
EQUIPMENT						
SUPPLIES						
TRAVEL						
RESEARCH-RELATED PATIENT COST						
OTHER EXPENSES						
SUBTOTAL DIRECT COST						
CONSORTIUM COST	DIRECT					
	INDIRECT					
TOTAL DIRECT COST						
TOTAL INDIRECT COST						
TOTAL DIRECT COST FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL INDIRECT COST FOR ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
TOTAL COST FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT					\$	
INSTITUTIONAL COST SHARE					\$	
GOVERNMENT COST SHARE					\$	
THIS AMOUNT MUST AGREE WITH THAT ENTERED ON THE COVER SHEET BOOKLET, ITEM #22						

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

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

Appendix 2

Biographical Sketches

BIOGRAPHICAL SKETCH			
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 postdoctoral 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 three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.			

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

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

Appendix 3

Regulatory Compliance Checklist/Form

This form **MUST** be completed and sent in when appendices are requested (on or about 1 February 1998).

Human Subjects: *Please read Appendix 5 before completing. Mark all that apply.*

- | | |
|---|--|
| ☐ Females | ☐ Males |
| ☐ Minor (under 18) | ☐ Minorities |
| ☐ Military, Active Duty | ☐ Military, Reserve |
| ☐ National Guard | ☐ Foreign |
| ☐ Inpatient | ☐ Outpatient |
| ☐ Clinical Trials | ☐ Other (specify): _____ |

Human Anatomical Substances: *Please read Appendix 5 before completing.*

In the proposed work, will human anatomical substances be used?

- ☐ Yes ☐ No

If yes, which anatomical substance(s) will be used (mark all that apply):

- | | |
|------------------------------|--|
| ☐ Blood | ☐ Saliva |
| ☐ Tissue | ☐ Established Cell Lines |
| ☐ Cells | ☐ Primary Cell Lines |
| ☐ DNA | ☐ Other (specify): _____ |
| ☐ Urine | |

Can the anatomical substance(s) indicated above be traced to a specific donor?

- ☐ Yes ☐ No

CONTINUED ON REVERSE

Animal Subjects: *Please read Appendix 6 before completing.*

In the proposed work, will animals be used?

- ☐ Yes ☐ No

In the proposed work, will animals be used by a subcontractor?

- ☐ Yes ☐ No

If yes to either of the above questions, which animal subjects will be used (mark all that apply):

- | | |
|--------------------------------|--|
| ☐ Primates | ☐ Ferrets |
| ☐ Frogs | ☐ Sheep |
| ☐ Rabbits | ☐ Dogs |
| ☐ Hamsters | ☐ Pigeons |
| ☐ Horses | ☐ Rodents |
| ☐ Cats | ☐ Guinea pigs |
| ☐ Chickens | ☐ Goats |
| ☐ Fish | ☐ Other (specify): _____ |

Safety Provisions: *Please read Appendix 7 before completing. Mark all that apply.*

- | | |
|---|--|
| ☐ Good Laboratory Practices (GLP) | ☐ Genetic Materials |
| ☐ Recombinant DNA | ☐ Biologicals/Toxins |
| ☐ Investigational Drugs | ☐ Hazardous Materials |
| ☐ Radioactive Materials | ☐ Other (specify): _____ |

Appendix 4

Certificate of Environmental Compliance

The offeror currently ____ IS ____ IS NOT (check appropriate category) in compliance with applicable national, state, and local environmental laws and regulations. (If not in compliance, attach details and evidence of approved mitigation measures.)

The offeror has examined the activities encompassed within the proposed action entitled
“ _____ ”

(enter title and/or Solicitation number and Principal Investigator's name), for compliance with environmental laws and regulations. The offeror states that the conduct of the proposed action

1. WILL NOT violate any applicable national, state, or local environmental law or regulation.
2. WILL NOT have a significant impact on the environment.

The offeror agrees that if the work required under the proposed action at any time results in a significant impact on the environment or a violation of any applicable environmental law or regulation, the offeror will immediately take appropriate action, to include notifying and/or coordinating with the appropriate regulatory agencies as required by law and notifying the Contracting Officer.

Name of Official Responsible for
Environmental Compliance

Signature

Title

Date

Name of Organization

Appendix 5

Research Involving Human Subjects and/or Human Anatomical Substances (includes DNA, cells, tissues, blood, etc.)

The intention of this appendix is to provide clear, concise information that will enable each Principal Investigator to prepare documentation for human use and regulatory compliance review by the U.S. Army Medical Research and Materiel Command (USAMRMC), Deputy Chief of Staff for Regulatory Compliance and Quality (RCQ), Human Use Review and Regulatory Affairs (HURRA). A synopsis of the guidance contained in the code of Federal Regulations, DOD Directives, and Army Regulations is provided at the end of this appendix (page 72). If only anatomical substances will be used, see below (Section A) for guidance. If human subjects or data about human subjects (inclusive of database studies) will be used, see pages 62-73 (Section B). These requirements may differ from those of other funding agencies.

Section A

Guidance for Use of Human Anatomical Substances

1. **GENERAL:** It is important to note clearly what type of human anatomical substances will be used, and how the substances will be used, in the research study. This section provides guidance for use of human blood, tissue, urine, saliva, cells, established cell lines, primary cell lines, DNA, and other associated substances.
2. **SPECIFIC GUIDANCE:**
 - a. **Human Blood, Tissue, Urine, Saliva, DNA, etc.**
 1. If the blood, tissue, urine, saliva, DNA, or other anatomical substance used in the study contains no personal identifiers and was not obtained for the purpose of this research (existing), the study is considered to be exempt from human use regulations. The Optional Form 310 should be completed and signed by the Chair of the local Institutional Review Board, indicating the study is exempt. It should be noted in the comments block that the study will use existing blood, tissue, urine, saliva, DNA, etc. with no personal identifiers linking the substance to the donor. This will be the sole document required for submission of the Human Use Appendix for this type of research.
 2. If the blood, tissue, urine, saliva, DNA, or other anatomical substance used in the study does contain personal identifiers or was obtained specifically for the purpose of this research, the study is considered to be minimal risk. An informed consent document written according to instructions in Section B must be prepared (See pages 66-69). The Optional Form 310 must be completed and signed by the Chair of the local Institutional Review Board, indicating the study is minimal risk. The consent form and completed Optional Form 310 will be the documents required for submission of the Human Use Appendix for this type of research.

b. Cells, Established Cell Lines, Primary Cell Lines, etc.

It should be clearly indicated how these anatomical substances were obtained. If the cells were purchased, it should be indicated from whom the purchase was made (or will be made). The use of these substances is considered exempt from human use regulations. The Optional Form 310 should be completed and signed by the Chair of the local Institutional Review Board, indicating the study is exempt. It should be noted in the comments block how the substances were obtained, purchased, etc. This will be the sole document required for submission of the Human Use Appendix for this type of research.

- 3. OPTIONAL FORM 310:** A copy of an Optional Form 310 is included on page 73. This form is also available at the following World Wide Web Site: <http://mrmc-rad6.army.mil/documents.html>
- 4. QUESTIONS:** Questions regarding the use of human anatomical substances should be directed to fax number (301)619-7803.
- 5. SUGGESTIONS:** Suggestions for improving or clarifying this section should also be directed to fax number (301)619-7803.

Section B

Guidance for Use of Human Subjects

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5. COPY OF THE OPTIONAL FORM 310	73

1. **GENERAL:** Each protocol submission should include a protocol, a consent form, and a completed Optional Form 310. If applicable, a copy of the advertisements, questionnaires, case report forms, IND information, and other related information should be provided with the Human Use Appendix. **All revisions to the protocol, consent form, advertisements, questionnaires, and other related study documentation must be reviewed and approved by the HURRA prior to implementation.**

2. **SPECIFIC GUIDANCE:**

a. **Protocol Review Checklist:** This checklist is designed to assist the applicant in preparing a protocol. If an item does not apply, please disregard.

- **PROJECT TITLE.** The consent form title must match that of the project.
- **PHASE.** For Food, Drug, and Cosmetic Act regulated medical products, designate as a Phase I, II, III, or IV protocol.
- **PRINCIPAL INVESTIGATOR.** The complete name, address, and phone number of the Principal Investigator must be listed at the top.
- **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.
- **TIME REQUIRED TO COMPLETE.** The month/year of expected start and completion dates must be listed.
- **PLAN.** Outline exactly the proposed methodology in enough detail to show a clear course of action. Technological reliability and validity of procedures should be indicated, and chronological order should be followed. Minimum guidance for the plan includes:
 - Selection of subjects
 - Number of subjects
 - Age range
 - Sex
 - Inclusion criteria/diagnostic criteria for entry/exclusion criteria (If women and/or minorities will be excluded, a justification as to why must be included.)
 - Evaluations prior to entry
 - Source of subjects
 - Subject identification (Describe code system to be used.)
 - Subject assignment
 - Risks to the subject
 - Precautions to be taken to minimize/eliminate risks
 - Specific medical or nursing care that will be needed
 - Description of project medication(s) or device(s) (If investigational, provide the IND number and sponsor.)
 - Complete names and composition of all medication(s)/device(s)/placebo(s)
 - Source of medication(s)/device(s)/placebo(s)
 - Place where study medication(s) will be stored
 - Dose range/dose schedule/administration
 - Washout period (The washout or pre-drug period must be carefully noted.)

- Duration of drug or device treatment
- Accompanying medications (Those allowed/disqualified)
- Antidotes to be available
- Copy of the medication/device label
- Evaluations made during/following project

NOTE: IT IS VERY IMPORTANT TO STATE IN THE PROTOCOL WHO IS ACTUALLY GOING TO PERFORM THE FOLLOWING:

1. Specimens to be collected
2. Schedule and amounts
3. Evaluations to be made on specimens
4. Storage (Include storage locations and whether special conditions are required.)
5. Labeling and disposition
6. Clinical assessments (Include how adverse effects are to be recorded.)
7. Vital signs
8. Follow-up procedures
9. Disposition of data (Where stored and for how long? Note: Records for IND studies must be kept until two years after an NDA/license for the investigational drug is approved/issued or for two years after the IND is withdrawn.)
10. Biostatistical reviews
11. Departure from protocol for individual subjects (When allowed, who will be notified; include HURRA.)
12. Modification of protocol (Describe the procedure to be followed if the protocol is modified. Include HURRA.)
13. Statement pertaining to disposition of unused drug
14. Use of information/publications arising from study
15. Personnel to conduct project (Names, positions, and phone numbers. Include the medical monitor. Attach a short biographical sketch. Include a resume of education, research training, and list of publications for each person.)

THE FOLLOWING SIGNATURES ARE REQUIRED FOR ALL PROTOCOLS:

1. Signature of Principal Investigator, date, with the accompanying statement--
"I have read the foregoing protocol and agree to conduct the study as outlined herein."
2. Signature of appropriate approving official and date.

ADDITIONAL CONSIDERATIONS:

- ✓ **A medical monitor must be assigned to human subjects research involving greater than minimal risk. The name and the curriculum vitae of the medical monitor must be provided. This individual should be a qualified physician, other than the Principal Investigator, who is not associated with the protocol, is able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and will monitor the subjects during the conduct of the study. (For multi-center studies involving greater than minimal risk, a medical monitor must be assigned to each site.)**

- ✓ If **HIV screening** is to be done, the consent form must further state that results will be provided to the subject and that medical referrals and follow-up will be available to subjects found to be HIV positive.
- ✓ A **science review** should be documented.
- ✓ The **method of determining pregnancy** status in women of childbearing potential must be specified, if applicable. Also, the time that will elapse between the pregnancy test and exposure to test procedures or medical products must be documented. Serum pregnancy tests are required for all clinical medical product studies. For IND studies, serum pregnancy testing is required within 48 hours prior to the start of the study.
- ✓ For **IND studies** that include females of childbearing age, any risks to the developing fetus should be outlined in the consent form.
- ✓ A letter from the Radiation Protection Officer at the study site approving the use of **radio-labeled products** must be included, if applicable.
- ✓ If there will be **collaborators** in the study, all letters of collaboration must be included.
- ✓ If the project is conducted in a **foreign country**, a letter of approval from the Ministry/ Minister of Health or equivalent approving official from the foreign country must be included.
- ✓ If a foreign study, the **foreign version of the consent form** must be included. In addition, the following statement and information is required on the English-language version of the translated consent form: "I certify that this is an accurate and true translation." The translator's signature, name, address, phone number, and fax number should also be included.
- ✓ If the study involves a **contagious disease**, any other studies going on in the isolation ward at the same time should be discouraged.

10 USC 980. An intent to benefit subjects who cannot give their own consent (minors, unconscious) must be shown. This intent must be clearly stated in the protocol and consent form.

- ✓ If **military subjects** are involved in a study and blood is to be drawn, they may be paid only for their blood donation and only up to \$50.00 per draw unless the study participation will be conducted during off-duty hours. This must be clearly stipulated. If payment will be provided to subjects in the study, it should be clearly stated who (military vs. civilian, if applicable) will be paid what amount, and when and how that payment will be made.

- ✓ All **payments to the subject** for their participation in the research must be made clear in both the protocol and the consent form. The pro-rated amount should subjects be withdrawn during the study must be indicated. It should also be indicated how and when payment will be made.
 - ✓ The collection of **minority group data** is suggested for inclusion in the study, e.g., American Indian or Alaska Native, Asian or Pacific Islander, Black (not Hispanic Origin), Hispanic, White (not Hispanic Origin), for future data analysis, in accordance with Public Law 103-160 and the Department of Health and Human Services and the Food and Drug Administration guidelines.
- b. **Elements of Informed Consent:** Informed consent is more than a document, it is a continual process. In preparing your informed consent document, please include all of the elements below that apply. 32 CFR 219 and 45 CFR 46 provide additional guidance for elements that are not listed below. If a multi-center study is proposed, the investigator must submit one consent form from each site for review and approval. That consent form must be used at each study site. Consent forms should be written in 8th grade reading level language. Use short, clear, simple, declarative sentences. Use non-medical language that is easily understood by the subject. *Elements listed in italics must be included in all consent forms.*
1. *Title of the study and complete address.*
 2. *Name of the Principal Investigator, and associate(s) if applicable, conducting the study.*
 3. *A statement that the study involves research.*
 4. *Purpose of the research.*
 5. Provide a **translation** of the consent form for subjects being enrolled in the study who do not comprehend English. The following statement and information is required on the English language version of the translated consent form: **"I certify that this is an accurate and true translation."** (The translator's signature, name, address, phone number, and fax number should also be included.)
 6. *Include a statement clearly indicating the expected duration of the subject's participation (the number of hours, days, etc.).*
 7. *Describe all procedures to be followed and identify any procedures that are experimental. These procedures should agree with the protocol.*
 8. *Briefly explain the study design relative to what will be done to the subject.*
 9. If a **placebo** is used, its contents should be described, in lay terms.
 10. Specify what is **required of the subject** (hospital visits, blood donation, etc.).

11. If **blood** is to be drawn (including serum pregnancy tests); the amount(s) to be drawn should be expressed in lay terms (for example, 2 teaspoons).
12. The subject should be advised that the IND/IDE is being used in this study. Clearly indicate that its use is investigational for the purposes of this research.
13. Include **risks or discomforts** to the subject. (This includes pregnancy and possible risks to the fetus.)
14. Will **pregnant women** be excluded and/or withdrawn from the study?
15. *Risks should include risks unique to the study; estimate their severity and likelihood; and/or compare these risks with risks the subject might encounter in the course of his/her daily activities. If similar research has been conducted in the past, describe the incidence of adverse effects or injuries occurring in previous subjects.*
16. *Benefits of participation in the study should be listed.*
17. *Alternative procedures should be disclosed.*
18. **Payment** for study participation should be disclosed (see page 66).
19. *Confidentiality of records identifying the subject must be described.*
20. *The following statement is MANDATORY for studies utilizing civilians:*
"Representatives from the U.S. Army Medical Research and Materiel Command (and, where applicable, the Food and Drug Administration, and the U.S. Army Medical Department Center and School) may inspect the records of the research in their duty to protect human subjects in research."
21. *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. Representatives of the U.S. Army Medical Research and Materiel Command [and the Food and Drug Administration] may inspect the records of the research."
22. *Medical care clause: "The Department of Defense is funding this research project. 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."*

23. **Points of Contact:**
- Answers to questions about the research study and in the event of a research-related injury to the subject should be provided by the investigator.*
 - Answers to questions about research subjects' rights should be provided by the local IRB or legal office.*
24. *A statement should be included that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*
25. *The Signature Block should include the date, signature, typed/printed name, and permanent address of subject and signature and typed/printed name of witness. If using Department of the Army active duty soldiers, contact Human Use Review and Regulatory Affairs for the appropriate Department of the Army form.*
26. *The subject and witness should initial and date all but the last page.*
27. **If blood, tissue, or body product samples** will be drawn in the study for possible future use in another protocol, the following statement **must be included**: "I understand that there is a possibility that the [blood, tissue, body fluids--specify what type] that I am providing under this study may also be used in other research studies and could potentially have some commercial applicability."
- If, indeed, it is anticipated that the samples donated by the volunteer will be used in other studies, an **additional donation form** must be prepared for signature by the volunteer that states "I voluntarily and freely donate any and all [blood, tissue, body fluids--specify what type] to the [name of the institution] and the U.S. Government and hereby relinquish all right, title, and interest to said items." The title of the study should be inserted at the top of the form.
28. *It should be clearly indicated whether the subject will be asked to pay any Costs associated with this study. If so, list what tests, etc. for which the subject will be responsible for paying. Also, if the cost of the study drug will be charged to the subject, it should be indicated.*
29. **If pregnant women** will be excluded, the following statement (or equivalent) must be included: "In order to participate in this study, you should have avoided becoming pregnant from the first day of your most recent menses. You should avoid becoming pregnant for at least [time period in days, weeks, or months] after [study end date, receipt of drug, etc.]. Pregnancy within [time period in days, weeks, or months] after [study end date, receipt of drug, etc.] may create a potential risk to the unborn baby. To avoid becoming pregnant, you should either abstain from sexual relations or practice a method of birth control. The only ways to completely avoid risk to the unborn baby are (1) to not become pregnant or (2) do not enter this study. Adverse effects might affect a developing fetus. Further, they might result in unknown risks of

deformities or death to the unborn baby. A negative pregnancy test does not absolutely prove that you are not pregnant. Regardless of the results of the pregnancy test that you were administered as part of the screening for this study, you should not participate if you think there is a possibility that you might be pregnant." Also, a statement should be included which directs the volunteer to notify the Principal Investigator if she becomes pregnant. Women should be notified if they will be withdrawn from the study should they become pregnant.

30. For all studies involving more than minimal risk, the following statement must be included in the consent form: "By enrolling in this study, you should understand that the United States Army Medical Research and Materiel Command (USAMRMC) will collect certain information about you, including your name, address, social security number, study name, and dates. The purpose is, first, to readily answer an individual's questions about their participation in research sponsored by the USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned of risks and to provide new information as it becomes available. The information will be retained in this database for a minimum of 75 years."

31. Each page should be dated using the date that the document was edited (ex: Ver 1.0/ March 1, 1997).

- c. **Optional Form 310 (OF 310):** Each institution must have an assurance of compliance with human use regulations. If an institution has a Multiple Project Assurance (MPA) on file with the Department of Health and Human Services (DHHS) Office for Protection of Research Risks, that assurance number should be documented on the OF 310 (page 73), Protection of Human Subjects Assurance/Certification/Declaration which replaced DHHS Form 596. If the institution does not have an MPA, an assurance application should be completed and sent with the protocol. A Department of Defense Assurance 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 that must use another institution's IRB. These assurance applications and the OF 310 can be downloaded from the World Wide Web Site: <http://mrmc-rad6.army.mil/documents.html>

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 HURRA reserves the right to determine whether the risk level is in compliance with all applicable regulations. If the study has been determined to be exempt, the investigator must clearly state the information requested in paragraph 3. **Risk Level Determination (exempt, minimal, or greater than minimal risk) should be indicated in the comments section.**

- d. **Advertisement:** If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the IRB-approved advertisement must be provided. IRB review of advertisements is necessary to ensure the information is not misleading to the subjects participating in IND studies. The FDA has established guidelines on advertisements for subjects. General guidance includes: name and address of Principal Investigator, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.
- e. **Questionnaires, Case Report Forms, Study Instruments, etc.:** Include copies of all other applicable study-related documentation: questionnaires, case report forms, data sheets, etc.

3. ANSWERS TO FREQUENTLY ASKED QUESTIONS:

- a. **What is the Medical Care Provision?** - Civilians must be provided medical care, free of charge, if they are injured as a direct result of their participation while enrolled in research funded by the USAMRMC. The proposed recipient must agree to provide this medical care. This is a requirement for all protocols funded by the USAMRMC, regardless of risk level. The consent form guidance (detailed on pages 66-69) provides a recommended statement to inform research subjects of this requirement. If the proposed recipient wishes to use similar wording, that wording will be reviewed upon submission. However, the proposed recipient's statement must concur with the USAMRMC policy of providing medical care, free of charge. Research will not be approved if the proposed contractor does not have a mechanism in place to provide this care. The mechanism used should be clearly stated in the consent form. Four possible mechanisms are as follows:
 - 1. The proposed recipient may absorb such costs into the institution's operating budget.
 - 2. 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.
 - 3. 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). This can only be negotiated with the U.S. Army Medical Research Acquisition Activity (the contracting organization).
 - 4. 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/her insurance company will be billed. The proposed recipient must also state, and agree to, an assurance that any payments not covered by the third-party insurance will be paid by the proposed recipient.

- b. **What is the Volunteer Registry Database?** - A confidential database has been created to enable the USAMRMC to fulfill its "duty to warn." The information contained in the database is cited on USAMRMC Form 60-R (Volunteer Registry Data Sheet). This data sheet will be provided to the Principal Investigator, upon approval of the use of human subjects. This form may be copied by the Principal Investigator. Data collection is required for all studies considered greater than minimal risk. All information obtained in this database is protected under The Privacy Act of 1974. Information about the study itself could be released to a requestor. However, personal identifying information (name, address, date of birth, social security number, etc.) may not, and will not, be released unless the subject (or legal guardian) provides written approval of such disclosure. Each subject on whom data are collected, upon written request to HURRA, RCQ, USAMRMC, may have access to their record, and only their record, contained in the database. The data sheets must be completed for each subject enrolled in the study. Upon completion of the phase, study, or project, these sheets should be forwarded to HURRA, RCQ, USAMRMC.
- c. **What is Risk Level Determination?** - HURRA has the obligation to ensure that the appropriate level of risk has been assigned to each project. In some cases, HURRA will make a different determination of risk from that of the proposed recipient's local Institutional Review Board (IRB). In those instances, HURRA will notify the Principal Investigator. In the case of exempt studies, the investigator must explain in the proposal what samples will be used, how and when they were collected, and what personal identifying information will be provided to the investigator. Database studies involving the use of personal identifying information are considered minimal risk, and a consent form must be provided.

Minimal risk studies involve tests and procedures that would mirror what the subject would normally encounter during a routine test or medical examination.

Greater than minimal risk studies involve all other procedures not considered routine. All investigational new drug studies are greater than minimal risk.

- d. **What are the Guidelines of Waiver of Informed Consent?** - Generally, the HURRA will not grant a waiver of informed consent for minimal risk and greater than minimal risk studies involving human beings as experimental subjects. However, minimal risk studies involving the use of data might be eligible for waiver, upon request by the investigator.
- e. **What is the HURRA Address?** - Should it be inconvenient to fax questions, comments, or suggestions, please feel free to write us at:

Commander
U.S. Army Medical Research and Materiel Command
Attention: MCMR-RCQ-HR
504 Scott Street
Fort Detrick, MD 21702-5012

- f. **What is a Medical Monitor?** - A medical monitor must be assigned to research studies with human subjects involving greater than minimal risk. The name and curriculum vitae of the medical monitor must be provided. This individual should be a qualified physician, other than the Principal Investigator, who is not associated with the protocol, is able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and will monitor the subjects during the conduct of the study.

4. POLICIES AND PROCEDURES:

Policies and procedures governing the use of human subjects and human anatomical substances are contained in the following documents:

- ◆ Code of Federal Regulation, Title 21 Part 50 (21 CFR 50)
- ◆ Code of Federal Regulation, Title 21 Part 56 (21 CFR 56)
- ◆ Code of Federal Regulation, Title 21 Part 312 (21 CFR 312) (when using investigational drugs/vaccines)
- ◆ Code of Federal Regulation, Title 21 Part 812 (21 CFR 812) (when using investigational devices)
- ◆ Code of Federal Regulation, Title 32 Part 219 (32 CFR 219)
- ◆ Code of Federal Regulation, Title 45 Part 46 (45 CFR 46), Subparts B, C, and D
- ◆ 10 United States Code, Section 980 (10 USC 980)
- ◆ Federal Acquisition Regulation 52.228-7 (FAR 52.228-7) (liability to third-party persons)
- ◆ Federal Acquisition Regulations 52.224-1 and 52.224-2 (privacy act information)

¶ Copies of the above can be obtained from:

U.S. Government Printing Office
North Capital & G Street, NW
Washington, DC 20401
Phone: (202)512-1800

- ◆ Department of Defense Directive 3216.2 (when using organs or tissues obtained at autopsy)
- ◆ Department of Defense Directive 6465.2
- ◆ Army Regulation 40-7 (when using investigational drugs/vaccines or schedule 1 controlled substances)
- ◆ Army Regulation 70-25

¶ Copies of these documents can be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Phone: (703)487-4650 or 4684

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 of 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 ☐ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION	2. Type of Mechanism ☐ GRANT ☐ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☐ 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 the 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 on 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. (with area code) 	12. Fax No. (with area code) 	14. Title 	
13. Name of Official 			
15. Signature 		16. Date 	

Appendix 6 Research Involving Animals

If using animals, please complete this entire appendix. If your subcontractor is using animals, please see item #9 below.

Department of Defense definition of animal: Any live nonhuman vertebrate.

Department of Defense 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 items listed below **must be addressed** in a proposal appendix entitled "Research Involving Animals." Questions concerning animal use should be directed to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick, MD 21702-5012
Phone: (301)619-2144
Fax: (301)619-7803

1. Literature Searches:

Alternatives. Identify the services (computer databases, literature searches, etc.) used to obtain information on alternatives to painful procedures. This includes alleviated pain. (The USAMRMC reserves the right to request evidence that an alternatives search was performed.)

Duplication. Identify the databases searched to ensure that unnecessary duplication of previous experiments does not occur. (The USAMRMC reserves the right to request evidence that a duplication search was performed.)

2. **Rationale/Justification for Using Animals:** Provide a statement of the rationale/justification for using animals. Were alternatives to animal use considered; i.e., computer modeling, cell cultures, etc.? **It is USAMRMC policy that alternatives to the use of animals be thoroughly investigated prior to submission of any proposal involving animals.**
3. **Species Identification and Rationale/Justification:** Identify the species of animals to be used and the rationale/justification for their use. Why was this particular animal model(s) chosen? Is there a unique quality or usefulness about this species that warrants its selection for use in the proposed research?

4. **Number of Animals Required and Rationale/Justification:** Provide the number of each species of animals to be used by experimental design and a scientific/mathematical rationale/justification for how it was determined to be the minimum number required to obtain valid results.
5. **Animal Research:** 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); and adjuvants and other injections (agent, dosage, route, and anatomical site of administration).
6. **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.
7. **Study Endpoint:** What is the projected endpoint or termination of the study for the animals?
8. **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.
9. **IACUC Approval:** Provide evidence of protocol approval from the Institutional Animal Care and Use Committee(s) (IACUC) 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).**
10. **USDA Inspection Report:** Include a copy of the most recent U.S. Department of Agriculture Inspection Report (APHIS Form 7008, Inspection of Animal Facilities, Sites or Premises) for the facility(s) where the animal research will be performed.
11. **Qualifications:** Provide information on the qualifications and training of personnel performing the animal procedures. It must specifically address the training and experience these personnel possess in using and manipulating the species of animals to be used in the proposal.
12. **Accreditation:** One of the following must be provided for each facility where the animal research will be conducted:
 - Evidence that the facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC-I).
 - 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.

- A statement signed by the Institutional Official that the care and use of animals will be done according to the National Research Council 1996 "Guide for the Care and Use of Laboratory Animals" and applicable Federal regulations.

13. Principal Investigator Signed Assurances: The Principal Investigator must provide the following signed assurances:

- 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.
- 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.
- I accept full responsibility for the proper care and use of the animals during the conduct of research outlined in the proposal.
- I verify that I have made a reasonably good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
- 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.
- 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 are used.

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

Appendix 7

Safety Program Plan

Each of the items below must be addressed in a proposal appendix entitled "Safety Program Plan" and must be prepared specifically for this proposal. Each section should be operation/research specific and addressed in order. Those items that do not apply to the proposed research will be labeled as "not applicable" or "N/A." Institutional safety manuals may be referenced; however, do not send copies of safety manuals.

1. The 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 the laboratory conditions. (Recipient name) shall be held responsible and liable for inaccuracies of the information provided, failure 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.

2. There shall be a description of the safety procedures relating to the research operations. 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 standing operating procedures to assure safe research and operations (to include emergency procedures); description of medical surveillance and support; and description of security controls necessary to ensure accountability.
3. There shall be a description of the safety programs (and corresponding training) in place to include but not be limited to Hazard Communications, Chemical Hygiene, and/or Bloodborne Pathogens.
4. There shall be a description of the facility where the research will take place. This should include a description of any ventilation system employed, fire protection equipment in place, and emergency equipment available.
5. There shall be a written hazard analysis and/or tests used to identify hazards. There shall be a description of each hazard identified, a hazard analysis based on maximum credible event, and a recommendation to minimize or eliminate hazard(s).
6. There shall be a written hazard analysis of potential health hazards posed as a result of the research to be performed. These should include infectious materials, bloodborne pathogens, toxic substances, and/or ionizing and non-ionizing radiation.

7. There shall be an identification of hazardous and environmentally unacceptable materials used in the research, use of possible alternative materials, and recommended actions to eliminate or reduce the use of hazardous materials. Address any exposure concerns to personnel or the public during research and/or operations (to include transportation, packing, and shipping) or resulting from laboratory research. Special disposal procedures should be considered.
8. If radioactive materials are used, the materials and the disposal method should be identified. A copy of the NRC-approved license shall be submitted (not a copy of the organization's sub-license). If no such material is to be used, it should be so stated.
9. Any research involving recombinant DNA must meet or exceed NIH Guidelines for Research Involving Recombinant DNA Molecules, latest edition. Included should be a discussion of these requirements. A copy of the organization's institutional Biosafety Committee approval or exemption of the research shall be submitted.
10. Any other safety data that pertain to the research that may clarify the program shall be submitted.

Appendix 8

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 1-24)

- obtain synthetic CR peptides (months 1-6)
- test the effect of synthetic peptides on the DNA-binding activity of CR (months 6-12)
- characterize the inhibitory potency of active peptides and attempt to optimize the effect by testing additional overlapping peptides (months 9-24)
- perform feasibility experiments to assess the ability of selected peptides to inhibit CR function in cultured cells (months 12-24)

Statement of Work

Follow-up Care for Men and Women with Lung 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 lung 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 6-12:

- 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 9-20:

- 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 2½-year study period.

Task 5. Interim Analyses, Months 20-24:

- 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 24-30:

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

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 13-24:

- 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.

Appendix 9

Country Codes (Listed Alphabetically)

ARGENTINA	AR	LEBANON	LB
AUSTRALIA	AU	MALAYSIA	MY
AUSTRIA	AT	MEXICO	MX
BELGIUM	BE	NETHERLANDS	NL
BRAZIL	BR	NEW ZEALAND	NZ
CANADA	CA	NORWAY	NO
CHILE	CL	PERU	PE
CHINA	CN	PHILIPPINES	PH
COLOMBIA	CO	PORTUGAL	PT
CONGO	CG	PUERTO RICO	RQ
COSTA RICO	CR	RUSSIA	RU
CZECH REP.	CS	SENEGAL	SN
DENMARK	DK	SINGAPORE	SG
EGYPT	EG	SLOVAKIA	SL
FINLAND	FI	SOUTH AFRICA	ZU
FRANCE	FR	SPAIN	ES
GERMANY	GY	SRI LANKA	CE
GHANA	GH	SUDAN	SD
GREECE	GR	SWEDEN	SE
GUATEMALA	GT	SWITZERLAND	CH
ICELAND	IL	TAIWAN	TW
INDIA	IN	THAILAND	TH
INDONESIA	ID	TRINIDAD/TOBAGO	TD
IRELAND	IE	TURKEY	TR
ISRAEL	IS	UGANDA	UG
ITALY	IT	UNITED KINGDOM	GB
JAMAICA	JM	URUGUAY	UY
JAPAN	JP	VENEZUELA	VE
KENYA	KE	VIRGIN ISLANDS	VI
KOREA	KR	WEST AFRICA	ZW
KOREA, P. D. R.	KP		