

Appendix A

Letter of Intent

Please fill out one form for each proposal you intend to submit in response to the Department of Defense Ovarian Cancer Research Program Fiscal Year 2000 Program Announcement. Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: 301-682-5521
E-mail: cdmp.pa@det.amedd.army.mil
Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRPO0-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

You may complete and submit this form via the Congressionally Directed Medical Research Programs web site at <http://cdmp.army.mil/?/announce/forms/>.

Principal Investigator's Name: _____

Principal Investigator's Address: _____

Phone Number: _____ Fax Number: _____

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

- Ovarian Cancer New Investigator Award
- Program Project Award

Content area that will be addressed in the proposal (check no more than five):

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

Proposal title and brief description: (For Program Projects, submit a single Letter of Intent. Include the title and a brief description of the Overall Program and *each* Research Project and Core Facility).

Use an additional page if needed. Please include the name of the principal investigator and applicant institution for tracking purposes.

Please send me the following:

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

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Appendix B

Proposal Preparation

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Proposal Preparation

1. Who May Apply

Eligible institutions include for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by or affiliated with an eligible institution. The U.S. Army Medical Research and Materiel Command (USAMRMC) is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

Please refer to Sections III-A and IV-A for additional Ovarian Cancer New Investigator and Program Project Award eligibility criteria, respectively.

Investigators are cautioned that awards are made to institutions. Should the principal investigator (PI) of a funded project leave the recipient institution, both the PI and an official of the recipient institution should contact the U.S. Army Medical Research Acquisition Activity (USAMRAA) awarding office prior to the PI leaving the recipient institution to discuss options available for continued support of the research project.

Historically Black Colleges and Other Minority Institutions

A goal of the Department of Defense (DOD) is to allocate funds for the Congressionally Directed Medical Research Programs' (CDMRP's) peer-reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders¹ and is intended to "advance the development of human potential, provide quality education, increase opportunities to participate in and benefit from Federal Programs and strengthen the capacity of targeted institutions." An institution's minority status is established by the Department of Education (DOEd). Proposals submitted to the DOD are assigned HBCU/MI status if they are so designated by the DOEd on the date that the Program Announcement is released. An updated DOEd list is posted on the CDMRP web site at <http://cdmrp.army.mil/?/announce/minority>. Any individual, regardless of ethnicity, nationality, or citizenship status, may apply for funding as long as they are employed by or affiliated with an eligible institution.

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

¹Executive Orders 12876, 12900, and 13021.

2. Proposal Acceptance Criteria

Compliance guidelines have been designed to present the proposal in an organized and easy-to-follow manner to scientific reviewers responsible for reviewing its merit. Scientific peer reviewers will expect to see a consistent, prescribed format for each reviewed proposal. Nonadherence to format requirements (such as font size, margins, line spacing, proposal components out of order) makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a poorer global priority score in scientific peer review. In particular, the review of applications containing more than the allotted number of pages will be restricted to the pages within the page limitations. **Excess pages may result in administrative rejection prior to scientific peer review.**

It is required that the instructions in this section be followed carefully. The proposal must be clear and legible and conform to the following format, spacing, font size, margin, and printing guidelines:

- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Margins: Minimum of 0.5 inch top, bottom, right, and left.
- Paper Size: 8.5 x 11.0 inches. (Note to international applicants: A4 paper will be accepted if the text of the proposal does not exceed 7.5 x 10.0 inches [approximately 19 cm x 25.5 cm].)
- Printing: Single-sided. (Double-sided pages are not acceptable, with the exception of article reprints.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Type Color: Black ink including all graphs, diagrams, tables, and charts. The proposal should contain only material that can be photocopied. Submitting investigators should be cautioned that color graphs or photographs may not reproduce in subsequent photocopies. Therefore, submission of color figures, tables, graphs, or photographs is not recommended. However, if color figures are submitted, it is recommended that they be provided in all copies.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)

- Type Font: 12 point, 10 pitch.

To assist applicants, the following example is included.

This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing. This illustrates the minimum font size and margins and the required line spacing.

3. Proposal Cover Booklet (Bubble Sheet)

Complete this form as described in Appendix C, Proposal Cover Booklet Instructions.

1. Each proposal should include one original plus three photocopies of the Proposal Cover Booklet.
2. Proposal Cover Booklets can be requested via phone, fax, e-mail, or mail at the addresses/ numbers in the Foreword. Please allow sufficient time for delivery by regular mail.

4. Peer Review Referral Page – Start section on a new page – No page limit

The Peer Review Referral Page must contain the following sections:

1. Proposal title.
2. PI's full name, including middle initial.
3. Keyword Descriptive Technical Terms. To assist the staff in assigning proposals to an appropriate scientific peer review panel, please specify the subject area of the proposed research/services. Then, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project (e.g., cell signaling, apoptosis, angiogenesis, drug delivery systems, gene therapy, x-ray crystallography, genetic counseling, quality of life, nuclear medicine, immunology, clinical oncology, nutrition).
4. Conflicts of Interest. Every effort is made to avoid real and apparent conflicts of interest during the peer review process. To assist the staff in this regard, list the names of all scientific participants in the proposal including the PI, co-investigators, research associates, research assistants, consultants, collaborators, and subcontractors. Provide the following information for each participant: name, degree(s), scientific discipline or medical specialty (e.g., radiology, immunology, clinical oncology, nutrition, pathology, cell biology, endocrinology), institutional affiliation(s), title(s), and role(s) on the proposed project.

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

The Proposal Title Page should include the following information:

1. Proposal title
2. Award Mechanism
3. PI's full name, including middle initial
4. PI's phone number, fax number, and e-mail address
5. Organization name and location (including city, state, zip or postal code, and country)
6. Name of administrative representative authorized to conduct negotiations
7. Phone number, fax number, and e-mail address of administrative representative authorized to conduct negotiations

Note: The proposed start date will be determined during contract negotiations.

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

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

7. Checklist for Proposal Submission Instructions

The Checklist for Proposal Submission found on page B-7 must be completed and submitted with an Ovarian Cancer New Investigator Award proposal and *each* Research Project and Core Facility as well as Overall Program section of a Program Project submission. Insert it immediately after the Table of Contents.

This page was intentionally left blank.

Complete and submit with your proposal immediately after the Table of Contents to confirm that all components are included in your application.

Checklist for FY00 OCRP Proposal Submission

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Proposal Cover Booklet (original plus 3 copies) |
| <input type="checkbox"/> | <input type="checkbox"/> | Proposal (original plus 30 copies) |

Original plus 30 copies includes:

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Peer Review Referral Page |
| <input type="checkbox"/> | <input type="checkbox"/> | Proposal Title Page (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Table of Contents (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Checklist for FY00 OCRP Proposal Submission |
| <input type="checkbox"/> | <input type="checkbox"/> | Structured Technical Abstract (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Lay Abstract (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Statement of Work (2-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Proposal Relevance Statement (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Proposal Body (10-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Abbreviations (1-page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | References (no page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | List of all Participants for the Entire Proposal (for Overall Program section in Program Project only) |
| <input type="checkbox"/> | <input type="checkbox"/> | Biographical Sketches (3-page limit per individual) |
| <input type="checkbox"/> | <input type="checkbox"/> | Existing/Pending Support (no page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Facilities/Equipment Description (no page limit) |

Administrative Documentation:

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Statement of Eligibility Form (for OCNIA* only; use form on page III-7). |
| <input type="checkbox"/> | <input type="checkbox"/> | Letter of Institutional Commitment (for Program Project Awards only) |
| <input type="checkbox"/> | <input type="checkbox"/> | Letters of Support and/or Collaborations (as applicable) |

Cost Estimates:

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | For OCNIA: |
| | | Detailed Cost Estimate |
| | | For Program Projects Awards: |
| <input type="checkbox"/> | <input type="checkbox"/> | Overall Program Cost Estimate (use form on page IV-13) |
| <input type="checkbox"/> | <input type="checkbox"/> | Detailed Cost Estimate (for each Research Project and Core Facility) |
| <input type="checkbox"/> | <input type="checkbox"/> | Total cost estimate matches Proposal Cover Booklet, item 4 |
| <input type="checkbox"/> | <input type="checkbox"/> | Instruments (no page limit) |
| <input type="checkbox"/> | <input type="checkbox"/> | Publications and Patent Abstracts (5-document limit) |

Additional Materials: Submit together in a manila clasp envelope.

- | | | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Structured Technical and Lay Abstracts (plus 2 copies of each) |
| <input type="checkbox"/> | <input type="checkbox"/> | 3½" disk containing files of technical and lay abstracts |
| <input type="checkbox"/> | <input type="checkbox"/> | Statement of Work (2 copies) |

By signing below, you confirm that your proposal contains the information requested above.

Signature of Applicant

Date

NOTE: Exceeding page limits may result in proposal rejection prior to peer review

* OCNIA: Ovarian Cancer New Investigator Award

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8. Proposal Abstracts – Start each abstract on a new page – 1 page each

Both a 1-page structured technical abstract and a 1-page lay (nontechnical) abstract are required. Each proposal abstract page should contain the title of the proposal and the name of the PI. **Do not include figures in either abstract.**

These abstracts are vitally important to the review of the proposal. **Programmatic review is based upon the Integration Panel’s review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.**

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, significance of the proposed work to the program’s goals, specific aims of the study, and study design.

Please use the outline below for preparing the structured technical abstract.

1. **Background** – Provide a brief statement of the ideas and reasoning behind the proposed work.
2. **Objective/hypothesis** – State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
3. **Specific Aims** – State concisely the specific aims of the study.
4. **Study Design** – Briefly describe the study design.
5. **Relevance** – Provide a brief statement explaining the potential relevance of the proposed work to the program’s goals. For example, how the study will prevent or improve the detection or treatment of the disease.

The lay abstract is intended to communicate the purpose of and rationale for the study to the nonscientific community. It should be composed in a way to make the scientific objectives of and rationale for the proposal understandable to nonscientifically trained readers.

In addition to the abstract pages contained within the proposal, submit two additional copies of each abstract in a manila clasp envelope, along with a 3½" computer disk containing the abstract files (clearly labeled with the name of the PI, institution, and word processing program). Submit abstracts in Word, WordPerfect, or ASCII format.

Abstracts of all funded proposals will be reproduced in an abstract book and posted on the CDMRP web site at <http://cdmrp.army.mil>. Thus, proprietary information should not be included in the abstract.

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

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

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

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

The Statement of Work must not exceed two pages of single-spaced typing. Several sample Statements of Work are included as a reference in Appendix D of this Program Announcement.

In addition to the Statement of Work pages contained within the proposal, submit two additional copies in the manila clasp envelope with the abstracts and disk.

10. Proposal Relevance Statement – Start section on a new page – 1-page limit

In the Proposal Relevance Statement, the investigator should describe how the proposed research/services is pertinent to one or more critical issues of the disease.

11. Proposal Body – Start section on a new page – page limit depends upon award mechanism

Each award mechanism has specific instructions for the description of the project and page limits. Investigators should refer to the specific evaluation criteria listed under the award mechanism to which they are applying to ensure that the necessary information is included.

12. Abbreviations – Start section on a new page – 1-page limit

Provide a glossary of all acronyms, abbreviations, and symbols used.

13. References – Start section on a new page – No page limit

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

14. Biographical Sketches – 3-page limit per investigator

Biographical sketches should be prepared for each of the key personnel listed on the budget page, including collaborating investigators. Each biographical sketch must not exceed three pages. The “Biographical Sketch” form can be found in Appendix E or downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>. A list of significant publications and a succinct summary of the investigator’s professional experience in the disease and/or potential for contribution to the field should be incorporated into the biographical sketch.

15. Existing/Pending Support – No page limit

List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. Proposals submitted under this Program Announcement should not duplicate other funded research projects. If no support exists, state “none.”

16. Facilities/Equipment Description – No page limit

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

17. Administrative Documentation – No page limit

Provide letter(s) from proposed collaborating individuals or institutions confirming collaborative efforts that are necessary for the project’s success. Other support documentation also may be required within specific award categories. Please follow specific instructions in each award mechanism. **Note: This section is not for additional data, figures, or other similar information.**

18. Detailed Cost Estimate – No page limit

Budget is a key consideration in both scientific peer and programmatic review; applicants are cautioned to use discretion in budget requests. Use the Detailed Cost Estimate form to prepare a detailed cost estimate of the proposed research/services. This form can be found in Appendix F or downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>. Please note that for Program Project submissions, the Overall Program Cost Estimate form found on page IV-13 must also be completed. The cost of preparing proposals in response to this Program Announcement is not considered an allowable direct charge to any resultant award.

19. Instruments – No page limit

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

20. Publications and Patent Abstracts – 5-document limit

Include up to five relevant publication reprints and patent abstracts. A patent abstract should provide a nonproprietary description of the patent application. If more than five such items are included in the submission, **the extra items will not be forwarded to scientific peer review**. Every copy of your proposal must include the same reprints and patent abstracts submitted with the original proposal.

21. Proposal Submission

Submit the following documentation to the address listed in the Foreword under Proposal Submission:

- Proposal:** **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated photocopies (stapled or binder-clipped) of the **entire package**. **Each copy must match the original, including reprints of any publications**. Do not use rubber bands, or spiral or three-ring binders.
- Proposal Cover Booklet(s):** **ONE** original (binder-clipped to the original proposal) and **THREE** photocopies (**not** binder-clipped to proposal copies).
- Abstract Pages:** **TWO** additional copies of both the structured technical abstract and the lay (nontechnical) abstract in a manila clasp envelope along with a 3½" computer disk containing the abstract files (clearly labeled with the name of the PI, institution, and word processing program). Format abstracts in Word, WordPerfect, or ASCII.

- Statement(s) of Work:** **TWO** additional copies of each Statement of Work in the same manila clasp envelope with abstract copies and disk.
- Packaging:** Package **ONE** complete proposal submission (original plus all materials requested above) per box. If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the proposal title and PI's name.
- Noncompliance:** Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in proposal rejection. Administrative reasons for **rejection** of all or part of proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**
- Submit the Proposal to:** Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP00-Program Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

22. Receipt Deadline

The receipt deadline for Program Project and Ovarian Cancer New Investigator Award proposals solicited in this Program Announcement is September 13, 2000 at 4 p.m. Eastern Time.

Any proposal received by the USAMRMC after the exact date and time specified for receipt shall **not** be considered unless it is received before FY00 award negotiations have been completed, and:

1. It was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. It was sent by U.S. Postal Service Express Mail Next Day Delivery to the address listed in section 21 (Proposal Submission) above (**do not use Second Day Delivery**) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline, or
3. It was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline for delivery by 4:00 p.m. Eastern Time on the due date, or

4. The Government, at its sole discretion, decides to accept the late proposal if it determines that no competitive advantage has been conferred and that the integrity of the competitive grants process will not be compromised.

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

23. Regulatory Compliance and Quality Requirements – To be submitted at a later date

Appendices G (Certificate of Environmental Compliance), H (Research Involving Human Subjects and/or Anatomical Substances), I (Research Involving Animals), and J (Safety Program Plan) outline Regulatory Compliance and Quality requirements. This information should be provided by the PI to the USAMRMC immediately upon request but **should not be submitted with the original proposal.**

Appendix C

Proposal Cover Booklet Instructions

You must submit an original Proposal Cover Booklet and three photocopies. For Program Project submissions, please note that a completed Proposal Cover Booklet is required for each Research Project and each Core Facility as well as for the Overall Program section. Additional Proposal Cover Booklets and instructions can be requested via phone, fax, e-mail, or mail at the addresses/numbers listed below. Please allow sufficient time for delivery by regular mail.

Phone: 301-682-5501
Fax: 301-682-5521
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRPO0-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

ATTENTION: 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. Take special care to see that the written and bubbled figures match exactly.

Marking Instructions

- Use a No. 2 pencil for bubbles.
- Type or print in block letters in the “nonbubble” areas. (Ink is acceptable.)
- Make solid marks that fill the circle completely.
- Make no stray marks on this form.
- Do not fold or tear form.

Specific Instructions for Completing the Proposal Cover Booklet

1. **Proposal Log Number.** (Leave blank.)
2. **Program Identifier and Award Mechanism.** Fill out with “OCRPO0” and award mechanism abbreviation selected from the list on the next page (e.g., OCRPO0, OCNIA). The mechanism must be filled out with careful consideration because it will determine, in part, how your proposal will be assigned and evaluated for funding.

<u>Award Mechanism</u>	<u>Mechanism Abbreviation</u>
Ovarian Cancer New Investigator Award	OCNIA
Program Project Award - Overall Program.....	PPA-OP
Program Project Award - Research Project	PPA-RP
Program Project Award - Core Facility	PPA-CF

3. **Award Mechanism Code.** Select one of the codes listed below. This must agree with the award mechanism listed in question 2.

<u>Award Mechanism</u>	<u>Mechanism Code</u>
Ovarian Cancer New Investigator Award	01
Program Project Award - Overall Program.....	02
Program Project Award - Research Project	03
Program Project Award - Core Facility	04

4. **Total Funding Requested from the Government.** Fill in the total dollar amount requested. This figure is inclusive of all direct and indirect costs for the entire proposed period of the research as indicated on the last line of page 2 of the Detailed Cost Estimate form. **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. Enter the amount in whole U.S. dollar figures only, and enter the numbers **flush** with the right-hand margin.

Note: For Program Project submissions, total dollar amounts must be provided in the Proposal Cover Booklet of each individual Research Project and Core Facility as well as the Overall Program section.

5. **Proposal Title.** Enter the title of the proposal, which may contain up to 160 characters. Please include the Research Project number and Core Facility letter in their respective titles. Capitalize the initial word and the first letter of each subsequent word, with the exception of prepositions, conjunctions, and articles. Please count each blank space as equivalent to one character.
6. **Principal Investigator (PI) Last Name, First Name, and Middle Initial.** The PI is the individual who is primarily responsible for the proposed research/services.
7. **Title.** Select the appropriate title for the PI.
8. **Degree(s) of Principal Investigator.** Select all that apply.
- 9-16. **Principal Investigator’s Mailing Address.** This is the primary address used to contact the PI. This is the address where the work will be performed. **Do not use the PI’s home address, and if possible, avoid the use of PO Boxes.** If applicable, indicate the PI’s organization (question 9), department (question 10), then street address (questions 11 and 12). Do not use abbreviations or acronyms of any kind in the address with the exception of state. Do not use formal terms such as “The” or “The Trustees of” when indicating the

organization. **When an organization or department name is not applicable, leave these sections blank and then fill out the PI's address, city, state, country, and zip code in the designated sections.** Applicants should use the appropriate country code listed below for question 15. International applicants should enter the international postal code in the space provided in question 16.

<u>Country</u>	<u>Code</u>	<u>Country</u>	<u>Code</u>	<u>Country</u>	<u>Code</u>
Argentina	AR	India	IN	Senegal	SN
Australia	AU	Indonesia	ID	Singapore	SG
Austria	AT	Ireland	IE	Slovakia	SL
Belgium	BE	Israel	IS	South Africa	ZU
Brazil	BR	Italy	IT	Spain	ES
Canada	CA	Jamaica	JM	Sri Lanka	CE
Chile	CL	Japan	JP	Sudan	SD
China	CN	Kenya	KE	Sweden	SE
Colombia	CO	Korea	KR	Switzerland	CH
Congo	CG	Korea, P.D.R.	KP	Taiwan	TW
Costa Rica	CR	Lebanon	LB	Thailand	TH
Czech Rep	CS	Malaysia	MY	Trinidad/Tobago ..	TD
Denmark	DK	Mexico	MX	Turkey	TR
Egypt	EG	Netherlands	NL	Uganda	UG
Finland	FI	New Zealand	NZ	United Kingdom ..	GB
France	FR	Norway	NO	United States	US
Germany	GY	Peru	PE	Uruguay	UY
Ghana	GH	Philippines	PH	Venezuela	VE
Greece	GR	Portugal	PT	Virgin Islands	VI
Guatemala	GT	Puerto Rico	RQ	West Africa	ZW
Iceland	IL	Russia	RU		

- 17-18. **Principal Investigator's Phone and Fax Numbers.** U.S. and Canada phone and fax numbers must be filled in completely. International phone and fax numbers, including city code and country code, should be indicated in the spaces provided.
19. **Principal Investigator's E-mail Address.** If the PI has access to e-mail, write the address in the space provided.
20. **Principal Investigator Demographics.** (Optional.) Indicate the PI's gender, ethnicity, and U.S. military affiliation.
21. **Key Personnel Demographics.** (Optional.) Select all that apply for key personnel's gender, ethnicity, and U.S. military affiliation.

Note: The data in questions 20 and 21 are being collected for demographic purposes and will be reported outside the Department of Defense (DOD) only as grouped data without personal identifiers. Disclosure of this information is voluntary.

22. **Work Performed in a U.S. Military Facility.** Please indicate yes, if some or all of the work will be performed at a DOD, Department of Veterans Affairs, a U.S. Uniformed Health Service institute, or other similar facility.
23. **Human Subjects.** Indicate all human subjects that will be used in this study. If no human subjects will be used, mark the appropriate bubble.
24. **Human Anatomical Substances.** Indicate all human anatomical substances that will be used in this study. If no human anatomical substances will be used, mark the appropriate bubble.
25. **Human Anatomical Substances Traceable to Donors.** Indicate whether human anatomical substances can be traced to a specific donor.
26. **Data Collection from Human Subjects.** Indicate all methods of all data collection on human subjects that will be used in this study. If no data collection from human subjects will be used, mark the appropriate bubble.
27. **Clinical Trials.** Indicate all of the types of clinical trials that are in the proposed work. If no clinical trials are proposed in this study, mark the appropriate bubble.
28. **Animal Subjects.** Indicate if animal subjects will be used in the proposed work and if animal subjects will be used by a subcontractor.
29. **Safety Provisions.** Select all that apply.
- 30-35. **Demographics of Human Test Subjects/Study Population of Interest.** If human subjects are being used, you **must** complete all these questions. If human subjects are **not** being used, leave questions 30 to 35 blank. For gender (question 30), demographics (question 31), ethnicity (question 32), age (question 33), general income (question 34), and U.S. military affiliation (question 35) indicate the appropriate descriptors for the human test subjects/study population that is being **specifically** targeted in the proposed research.
36. **Mentor Name.** Leave blank.
37. **Proposal Descriptors - Research Classification.** Choose **ONE** research classification from the following list that best describes the proposed work.

<u>Research Classification</u>	<u>Code</u>
Behavioral/Psychosocial Research	10
Clinical Research	20
Clinical Trials	30
Epidemiology/Public Health Research	40
Laboratory Research	50

38. **Proposal Descriptors – Congressionally Directed Medical Research Programs (CDMRP) Research Classification.** Select **ONE** primary four-digit code that best describes the proposed research from the CDMRP Research Classification list that begins on page C-8.
39. **Proposal Descriptors - CDMRP Research Classification.** Select **ONE** secondary four-digit code that best describes the proposed research from the CDMRP Research Classification list that begins on page C-8. If no other code applies, please use code “0000.”
40. **Proposal Descriptors - Common Scientific Outline.** Select **ONE** primary four-digit code that best describes the proposed research from the Common Scientific Outline that begins on page C-15.
41. **Proposal Descriptors - Common Scientific Outline.** Select **ONE** secondary four-digit code that best describes the proposed research from the Common Scientific Outline that begins on page C-15. If no code applies, please use code “0000.”
42. **Proposal Descriptors – Population-Based Study**
Is this a population-based study? If yes, code “9999.” If no code applies, please use code “0000.”
- 43-46. **Proposal Descriptors.** (Leave blank.)
47. **Administrative Representative Authorized to Conduct Negotiations.** Indicate the primary and secondary administrative contacts authorized to conduct negotiations on the PI’s behalf. The organization, address, and appropriate contact information should be provided. The organization listed is the organization that is submitting the proposal on the PI’s behalf. If the organization has a grants/contracts/business official, this is the individual authorized to negotiate potential awards. The signature of an institutional representative certifies that the institution has examined the PI’s credentials and verifies that the PI is qualified to conduct the proposed study and to use humans or animals as research subjects, if appropriate. **This signature is mandatory.** For Certifications and Assurances, refer to the U.S. Army Medical Research Acquisition Activity web site located at <http://www-usamraa.army.mil>, select “Assistance Agreements, Assistance Package Certifications and Assurances.”
48. **Organization Code.** (Leave blank.)
49. **Type of Organization.** Choose one organization code that best describes your institution from the list on the following page. Refer to the updated list of Department of Education-recognized Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) to determine HBCU/MI status. This list can be accessed on the CDMRP web site at <http://cdmrp.army.mil/?/announce/minority>.

<u>Type of Organization</u>	<u>Organization Code</u>
Business-Large	A
Business-Small/Disadvantaged	B
Business-Small/Woman-Owned	C
Business-Small/Other	D
Educational Institution-HBCU	E
Educational Institution-MI	F
Educational Institution-Other	G
Federal Government-Air Force	H
Federal Government-Army	I
Federal Government-Navy	J
Federal Government-Veterans Affairs	K
Federal Government-DOD	L
Federal Government-Other	M
Foreign (non-U.S.)	N
Nonprofit	O
Other Organization	P
State Government	Q

50. **Institution’s Official Proposal Control Number.** This is the number that the institution uses to track the proposal. This number, if available, should be provided by the institution’s grants/contracts/business office listed in question 47.

51. **Principal Investigator.** The PI must fill out this information and sign in the space indicated. **This signature is mandatory.**

52. **How Did You Hear about This Announcement?** Please indicate all sources from the following list that apply to this announcement.

<u>Source</u>	<u>Code</u>
CDMRP web site	A
CDMRP e-mail	B
CDMRP postcard mailing	C
Previously applied/watched for release date	D
Information from a colleague	E
<i>Science</i> Advertisement	F
<i>Commerce Business Daily</i> Advertisement	G
Advertisement in another technical journal	H
Advertisement in a technical meeting’s proceedings.....	I
Display at American Association of Cancer Research meeting	J
Display at Society of Behavioral Medicine meeting	K
Display at Federation of American Society of Experimental Medicine meeting	L
Display at Minority Health Professionals meeting	M
Display at American Urological Association meeting	N

Appendix C

Display at American Society of Clinical Oncology meeting O
Display at Complementary and Alternative Medicine meeting P
Display at Endocrine Society meeting Q
Display at Gynecology Oncology Group meeting R
Display at American Society of Human Genetics meeting S
Display at the Society for the Advancement of Chicanos and
Native Americans in Science meeting T
Display at American Society for Therapeutic Radiology and Oncology
meeting U
Display at Association of Military Surgeons of the United States meeting V

CDMRP Research Classification
(For questions 38 and 39)

Cell Biology: Covers the study of the cell and its structure, including cellular organization, regulation, composition, and function of normal and transformed cells.

- 0101 Cell cycle: Covers studies on the sequence and regulation of cellular events between mitotic divisions.
- 0102 Cellular structure: Covers the study of proteins that are involved in mediating the recognition and adhesion of cells to their substrates and to other cells to include adhesion, integrins, matrix, membrane bound proteins, and cytoskeletal components.
- 0103 Growth factors/Cytokines: Covers studies on polypeptides and their receptors that control the ontogeny and maintenance of tissue form and function.
- 0104 Oncogenes: Covers studies on genes whose mutation or overexpression promotes tumor development/malignant phenotype.
- 0105 Tumor suppressor genes: Covers studies on genes whose mutation or inactivation leads to tumor development/malignant phenotype.
- 0106 Metabolism: Covers studies on the sum of all physical and chemical processes by which an organism is produced and maintained as well as the transformation by which energy is made available for use by the organism.
- 0107 Signal transduction: Covers studies on the activation of intracellular response pathways.
- 0199 Not otherwise specified: Covers studies in cell biology not otherwise specified in the other research areas.

Genetics and Molecular Biology: Covers studies on the molecular structures and events underlying biological processes, especially the relation between genes and the functional characteristics they determine.

- 0201 Chromosome structure: Covers studies on the organization of the DNA into a chromosome and the accompanying chromosomal elements and staining and sequencing techniques.
- 0202 DNA damage and repair: Covers studies on the mechanisms of DNA damage as well as the enzymatic correction of errors in DNA structure and sequence.
- 0203 Genomic instability: Covers studies on genetic changes that result in new combinations of alleles and/or chromosomal modifications such as crossing over, deletions, translocations, and loss of heterozygosity.
- 0204 Familial and hereditary carcinogenesis: Covers studies of genes and their products that cause initiation, progression, and spread of cancer in familial or hereditary clusters.

CDMRP Research Classification (For questions 38 and 39) - continued

- 0205 Transcription, translation, and modification: Covers studies on the process by which genetic information encoded in a gene is converted into RNA and protein and subsequent post-translational modifications.
- 0206 Genomics and Proteomics: The study of the total set of genes and their functional products and proteins expressed in a cell.
- 0299 Not otherwise specified: Covers studies in molecular biology and genetics not otherwise specified in the other research areas.

Endocrinology: Covers studies on structure and function of endocrine glands, their products, and their control to include hormones and their receptors.

- 0301 Clinical endocrinology: Covers studies of hormonal functions, ligand interactions, and metabolism as it relates to bedside and clinical applications.
- 0302 Endocrine carcinogenesis: Covers studies on the role of hormones in the initiation and support of cancer growth.
- 0303 Hormone metabolism: Covers studies of the biosynthesis, degradation, and enzymatic interconversions of hormones and structural analogs.
- 0304 Hormone receptors: Covers studies related to membrane-bound or intracellular molecules that bind with high affinity to, or respond to, hormones.
- 0305 Mechanism of hormone action: Covers studies of ligand and its receptor interaction on targeted metabolic processes and the downstream consequences of this interaction.
- 0399 Not otherwise specified: Covers studies in endocrinology not otherwise specified in the other research areas.

Pathobiology: Covers studies on the pathological cell and tissue specifically related to cancer to include cellular structure, organization, regulation, composition, and function.

- 0401 Angiogenesis: Covers studies on the neovascularization associated with tumor growth and the proteins and genes that mediate this phenomenon.
- 0402 Apoptosis: Covers studies on the process of a particular form of a cell death, programmed cell death, that is characterized by specific morphologic and biochemical properties.
- 0403 Biomarkers: Covers studies on cellular constituents whose presence and/or concentration might serve as an indicator of the predisposition, presence, or progression of cancer.
- 0404 Environmental carcinogenesis: Covers studies on the influence and/or linkage of chemicals and other environmental pollutants with high risks of specific types of cancer.

CDMRP Research Classification (For questions 38 and 39) - continued

- 0405 Progression/invasion/metastasis: Covers studies on cell proliferation from the time of initial transformation to metastasis.
- 0406 Stromal-epithelial interactions: Covers studies on the role of the interaction of the stromal and epithelial elements in the initiation of cancer.
- 0499 Not otherwise specified: Covers studies in pathobiology not otherwise specified in the other research areas.

Immunology: Covers studies of the cell-mediated and humoral aspects of immunity and immune responses excluding therapeutic manipulations of the immune system.

- 0501 Molecular: Covers studies to identify immune markers and characterize antibody structures as well as genetic engineering and progressive cloning studies.
- 0502 Tumor: Covers studies of interaction between the immune system and tumor(s).
- 0503 Regulation of the Immune Response: Covers studies of mechanisms that up- or downregulate the immune system.
- 0504 Immunodeficiency: Covers studies of inadequacies in the cell-mediated or humoral aspects of immune response or its regulation.
- 0505 Autoimmunity and Autoimmune Disease: Covers studies of specific immunity to constituents of self.
- 0599 Not otherwise specified: Covers studies in immunology not otherwise specified in the other research areas.

Primary Prevention: Covers studies that prevent the occurrence of disease in persons who are well.

- 0601 Lifestyle: Covers studies of the contributions and consequences of lifestyle and behavioral factors on disease risk, as well as studies to test lifestyle interventions to reduce disease risk. Lifestyle factors included in this category are, for example, exercise and diet.
- 0602 Chemoprevention: Covers studies on the effect(s) of drugs to prevent occurrence of disease.
- 0603 Nutrition: Covers studies on the contributions and consequences of diet and/or nutrition on disease risk, as well as to test educational and diet and/or nutritional interventions intended to prevent the occurrence of disease.
- 0604 Genetic risk: Covers studies among individuals with defined gene composition and genetic mutations to test interventions intended to prevent the occurrence of disease.
- 0699 Not otherwise specified: Covers primary prevention studies not otherwise specified in the other research areas.

CDMRP Research Classification (For questions 38 and 39) - continued

Detection and Diagnosis: Covers the study of improved detection and diagnostic techniques.

- 0701 Biomarkers: Covers the study of the use of compounds detectable in blood, body fluids, or tissues, whose detection can be used for screening or diagnosis.
- 0702 Cell/tissue sampling: Covers the study of methods for collecting cell or tissue samples and studies on the most effective testing of these samples for the detection or diagnosis of disease.
- 0703 Computer-aided diagnosis: Covers the study of computer programs and artificial intelligence systems to assist in the evaluation of radiographic or other diagnostic information.
- 0704 Digital imaging: Covers the study of capturing, storing, viewing, and analyzing radiographic or other images in a digital format.
- 0705 Magnetic resonance imaging: Covers the study of visualization of structures in the body by use of oscillating magnetic fields and analysis of the resulting radio frequencies produced.
- 0706 Nuclear medicine imaging: Covers the study of image production or count acquisition after the administration of a radionuclide.
- 0707 Ultrasonography: Covers the study of visualization of structures in the body by recording the reflections of high frequency sound waves directed into the tissues.
- 0708 X-ray imaging: Covers the study of visualization of structures in the body by externally applied ionizing radiation.
- 0709 Other imaging: Covers the study of imaging modalities not otherwise specified in the other research areas.
- 0799 Not otherwise specified: Covers studies in diagnostic modalities not otherwise specified in the other research areas.

Clinical and Experimental Therapeutics: Covers studies on agents to assess their use in treatment. Includes model systems ranging from cell cultures to animals and humans.

- 0801 Chemotherapy: Covers the study of using drugs or a combination of drugs to kill or halt the growth of cancer cells.
- 0802 Pharmacology: Covers the screening, testing, and studies of mechanisms of action of treatment agents, modification of existing agents, and the study of the routes of administration. Includes drug delivery.
- 0803 Drug resistance/multidrug resistance: Covers the study of the mechanisms, treatments, and prevention of classic MDR and other forms of drug resistance.
- 0804 Targeted therapies (conjugated toxins): Covers the development, testing, and study of chimeric compounds that combine a targeting component with a toxic or therapeutic component.

CDMRP Research Classification (For questions 38 and 39) - continued

- 0805 Vaccines: Covers the study of treatment of disease with agents designed to elicit immune responses to specific antigens.
- 0806 Immunotherapies: Covers the study of treatment of disease by passive immunization or by the use of agents designed to potentiate or suppress actions of leukocytes. Excludes vaccines.
- 0807 Radiotherapy: Covers the study of using ionizing radiation to treat disease or kill cells.
- 0808 Hormonal therapy: Covers the study of disease by removing, blocking, or adding hormones.
- 0809 Gene therapy (includes vector development): Covers the study of treatment that modifies or inserts genes into cells to improve the body's natural ability to fight disease or to make the tumor more sensitive to other therapies. Includes gene vector development and antisense technologies.
- 0810 Photodynamic therapy: Covers the study of light-activated substances in treating disease.
- 0811 Antiangiogenics: Covers the study of using substances that inhibit blood vessel formation accompanying tumor growth.
- 0812 Surgery: Covers studies on procedures designed to remove or repair tissue cells.
- 0813 Hyperthermia: Covers the study of localized or systemic temperature increases for either direct therapeutic effect or enhancing the effectiveness of other therapies.
- 0899 Not otherwise specified: Covers studies in clinical and experimental therapeutics not otherwise specified in the other research areas.

Complementary and Alternative Medicine: Covers studies of treatments and practices that reflect nontraditional forms of intervention or supportive methods that complement or add to mainstream treatments.

- 0901 Neutraceuticals: Covers studies of nutritional, vitamin and/or dietary supplements and/or applications of nutritional, vitamin, and/or dietary supplements that reflect nontraditional forms of intervention or supportive methods that complement or add to mainstream treatments.
- 0902 Homeopathy: Covers studies of homeopathic approaches that attempt to stimulate the body to recover itself. These approaches reflect nontraditional forms of treatment intervention or supportive methods that complement or add to mainstream treatments.
- 0999 Not otherwise specified: Covers studies of the application of non-neutraceutical or homeopathic approaches (e.g., meditation, biofeedback, massage) that reflect nontraditional forms of treatment or supportive methods that complement or add to mainstream treatments.

CDMRP Research Classification (For questions 38 and 39) - continued

Health Care Delivery: Covers studies assessing the delivery of disease prevention, detection, treatment, and rehabilitation services.

- 1001 Health care setting: Covers studies describing and/or assessing interventions or policies to enhance the delivery of disease prevention, detection, treatment, and rehabilitation services in medical systems and medical care settings, including for example, patterns of care assessments, cost effectiveness studies, provider education, and patient education in a medical care setting.
- 1002 Communities: Covers studies describing and/or assessing interventions and/or policies for reaching and/or influencing populations in community and other nonmedical settings in order to improve the delivery of disease prevention, detection, treatment, and rehabilitation services. Studies include, for example, community outreach interventions and public education programs.
- 1099 Not otherwise specified: Covers health care delivery studies not otherwise specified in the other research areas.

Behavioral and Psychosocial Sciences: Covers studies describing knowledge, attitudes, and behavior in defined populations and assessing the relationship(s) between behavioral and social functioning and disease initiation, progression, detection, treatment, and rehabilitation.

- 1101 Basic behavioral: Covers descriptive studies of knowledge, attitudes, and behavior in defined populations as well as studies of the basic relationships between biology and behavioral factors and disease.
- 1102 Disease symptom management: Covers studies of behavioral and social factors (e.g., knowledge, attitudes, and behavior) that influence disease-specific symptoms and/or interventions to relieve patients of disease symptoms, reduce treatment side-effects, and through the reduction of disease-specific symptoms, enhance patients' quality of life.
- 1103 Quality of life: Covers studies of behavioral and social factors (e.g., knowledge, attitudes and behavior) that contribute to quality of life, or interventions designed to enhance quality of life, or the quality of life consequences that result from the actions of patients, caregivers, and/or providers among individuals with or at risk for disease, excluding actions specific to the management of disease symptoms. Studies include, for example, minimization of menopausal symptoms, partner support, and psychosocial functioning.
- 1104 Decision making: Covers studies of factors (e.g., knowledge, attitudes, behavior, genetic counseling, risk assessment) that contribute to patient, caregiver, or provider decision making regarding diagnosis, treatment, and/or rehabilitation, including patient participation in clinical trials.
- 1199 Not otherwise specified: Covers behavioral and psychosocial science studies not otherwise specified in the other research areas.

CDMRP Research Classification (For questions 38 and 39) - continued

Epidemiology: Covers population and patient-based observational research studies of the distribution of disease as well as the behavioral and/or biological determinants of disease risk, initiation, progression, detection, and/or prognosis.

- 1201 Descriptive epidemiology/surveillance: Covers population and patient-based observational research studies of the distribution of disease in defined populations.
- 1202 Behavioral epidemiology: Covers population and patient-based observational studies assessing the nature of associations between lifestyle and host factors and disease risk, initiation, progression, detection, prognosis, and/or treatment.
- 1203 Gene-environment epidemiology: Covers population and patient-based observational studies assessing the nature of associations and effect modification including molecular changes between genetic susceptibility, polymorphic genes, and environmental or host factors and disease risk, initiation, progression, and/or intermediate disease endpoints.
- 1204 Nutritional epidemiology: Covers population and patient-based observational studies assessing the nature of associations and effect modification between nutritional factors and disease risk, initiation, progression, detection, and prognosis.
- 1299 Not otherwise specified: Covers epidemiological studies not otherwise specified in the other research areas.

Research Resources: Covers support for the development and/or maintenance of institutional, regional, or national facilities to sustain biomedical research.

- 1301 Cancer training program: Covers support for extramural programs to train investigators.
- 1302 Registries: Covers support for development, maintenance, and study of registries (i.e., central agencies for the collection of pathologic material and related clinical, laboratory, x-ray, and other data in a specified field of pathology, organized so that the data can be properly processed and made available for study).
- 1303 Animal models: Covers support for the development of animal models of human diseases.
- 1304 Computer models: Covers support for the development and maintenance of computer modeling and information management systems.
- 1305 Cancer centers: Covers support for the development of core-supported, multiproject research programs integrated around a common theme.
- 1306 Statistical models: Covers support for the development of models for data analysis.
- 1399 Not otherwise specified: Covers studies in research resources not otherwise specified in the other research areas.

Common Scientific Outline
(For questions 40 and 41)

Biology

- 0011 Cancer related biology: Biology of the organism, organs, tissues, cells, and subcellular organelles. Developmental biology from conception to adulthood and the biology of aging. Study of normal functioning genes, their localization, identification, expression patterns, and functional studies of gene products. Studies of the immune system including cells, products, and functions. Extracellular matrix formation and interactions, cell-cell interactions. Genes and signals involved in growth stimulation or repression, including oncogenes (RAS, etc.) and tumor suppressor genes (p53, etc.) and hormones and growth factors such as estrogens, androgens, TGF-beta, and GM-CSF. General mechanisms of carcinogen metabolism and DNA damage, DNA repair pathways, and mutation fixation. Epigenetic mechanisms in the regulation of cell proliferation and behavior. Progression, including clonal evolution, tumor-immune system interactions; factors that influence clonal expansion or regression, tumor promotion. Metastasis, including studies involving cell-cell interactions, tumor-host interactions, cell motility, remodeling of cellular matrix, cell migration and clonal expansion at distant sites. Biology of tumor regression.
- 0012 Resources and infrastructure related to biology: Infrastructures related to discovery, for example, the Cancer Genome Anatomy Project. Informatics and informatics networks. Specimen resources (serum, tissue, etc.). Reagents, chemical standards, pharmaceuticals.

Etiology

- 0021 Exogenous factors: Lifestyle factors such as smoking, chewing tobacco, alcohol consumption, parity, diet, sunbathing, and exercise. Environmental and occupational exposures such as radiation, secondhand smoke, radon, asbestos, organic vapors, pesticides, and other chemical or physical agents. Infectious agents associated with cancer etiology, including viruses (Human Papilloma Virus-HPV, etc.) and bacteria (*helicobacter pylori*, etc.). Viral oncogenes and regulatory genes associated with cancer causation.
- 0022 Endogenous factors: Hormones and growth factors such as estrogen, androgens, TGF- β , and GM-CSF. Free radicals such as superoxide and hydroxide radicals. Genes known to be involved or suspected of being mechanistically involved in familial cancer syndromes, for example, BRCA1, Ataxia Telangiectasia, and APC. Genes suspected or known to be involved in “sporadic” cancer events, for example, polymorphisms and/or mutations that may affect carcinogen metabolism (e.g., CYP, NAT, and glutathione transferase). Tumor suppressor genes (p53, etc.) and oncogenes (RAS, etc.).
- 0023 Interactions of genes and/or genetic polymorphisms with exogenous and/or endogenous factors: Gene-environment interactions. Interactions of genes with lifestyle factors, environmental and/or occupational exposures such as variations in carcinogen metabolism associated with genetic polymorphisms. Interactions of genes and endogenous factors such as DNA repair deficiencies and endogenous DNA damaging agents such as oxygen radicals or exogenous radiation exposure.

Common Scientific Outline (For questions 40 and 41) - continued

0024 Resources and infrastructure related to etiology: Informatics and informatics networks, for example, patient databanks. Specimen resources (serum, tissue, etc.). Reagents and chemical standards. Epidemiological study methods. Statistical methodology or biostatistical methods.

Prevention

0031 Interventions to prevent cancer: Personal behaviors that affect cancer risk: Research on determinants of personal behaviors, such as diet, physical activity, sun exposure, and tobacco use that affect cancer risk. Interventions to change personal behaviors that affect cancer risk.

0032 Nutritional science in cancer prevention: Quantification of nutrients and micronutrients. Studies on the effect(s) of nutrients or nutritional status on cancer incidence. Dietary assessment efforts including dietary questionnaires and surveys. Development, characterization, and validation of dietary/nutritional assessment instruments.

0033 Chemoprevention: Chemopreventive agents and their discovery, mechanism of action, development, testing in model systems, and clinical testing.

0034 Vaccines: Vaccines for prevention, their discovery, mechanism of action, development, testing in model systems, and clinical testing.

0035 Complementary and alternative prevention approaches: Discovery, development, and testing of complementary/alternative prevention approaches such as herbs, supplements, or other interventions that are not widely used in conventional medicine or are being applied in different ways as compared to conventional medical uses.

0036 Resources and infrastructure related to prevention: Informatics and informatics networks, for example, patient databanks. Specimen resources (serum, tissue, etc.). Epidemiological (observational) studies. Clinical trials infrastructure. Statistical methodology or biostatistical methods.

Early Detection, Diagnosis, and Prognosis

0041 Technology development and/or marker discovery: Discovery of markers (e.g., proteins, genes) and/or imaging methods that are potential candidates for use in cancer detection, diagnosis, and/or prognosis.

0042 Technology and/or marker evaluation with respect to fundamental parameters of method: Preliminary evaluation with respect to laboratory sensitivity, laboratory specificity, reproducibility, and accuracy.

0043 Technology and/or marker testing in a clinical setting: Evaluation of clinical sensitivity, clinical specificity, and predictive value. Quality assurance and quality control. Inter- and intralaboratory reproducibility. Testing of the method with respect to effects on morbidity and/or mortality. Study of screening methods including compliance, acceptability to potential screenees, and receiver-operator characteristics.

Common Scientific Outline (For questions 40 and 41) - continued

0044 Resources and infrastructure related to detection, diagnosis, or prognosis: Informatics and informatics networks, for example, patient databanks. Specimen resources (serum, tissue, images, etc.). Clinical trials infrastructure. Epidemiological studies pertaining to risk assessment, detection, diagnosis, or prognosis. Statistical methodology or biostatistical methods.

Treatment

0051 Localized therapies - discovery and development: Discovery and development of treatments that target the organ and/or neighboring tissue directly including but not limited to surgical interventions and radiotherapy.

0052 Localized therapies - clinical applications: Clinical testing and application of treatments that target the organ and/or neighboring tissue directly including but not limited to surgical interventions and radiotherapy. Phase I, II, or III clinical trials of promising local therapies.

0053 Systemic therapies - discovery and development: Discovery and development of systemically active treatments such as cytotoxic, hormonal agents, novel systemic therapies such as immunologically directed therapies (vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors and differentiating agents. Defining molecular signatures of cancer cells. Identifying molecular targets for drug discovery. Includes mechanistic studies of cellular metabolism, combinatorial chemical synthesis, drug screening, development of high throughput assays, and testing in model systems.

0054 Systemic therapies - clinical applications: Clinical testing and application of systemically administered treatments such as cytotoxic, hormonal agents, novel systemic therapies such as immunologically directed therapies (vaccines, antibodies), gene therapy, angiogenesis inhibitors, apoptosis inhibitors, and differentiating agents. Phase I, II, or III clinical trials of promising systemic therapies.

0055 Combinations of localized and systemic therapies: Development and testing of combined approaches to treatment.

0056 Complementary and alternative treatment approaches: Discovery, development, and testing of complementary/alternative treatment approaches such as herbs, supplements, natural substances, or other interventions that are not widely used in conventional medicine or being applied in different ways as compared to conventional medical uses.

0057 Resources and infrastructure related to treatment: Informatics and informatics networks, for example, clinical trial networks and databanks. Mathematical and computer simulations. Specimen resources (serum, tissue, etc.). Clinical trial groups. Statistical methodology or biostatistical methods. Drugs and reagents for distribution and drug screening infrastructures.

Common Scientific Outline (For questions 40 and 41) - continued

Cancer Control, Survivorship, and Outcomes Research

- 0061 Survivorship issues (post-treatment concerns): Quality of life – post-treatment. Pain management – post-treatment. Psychological impacts of cancer survivorship. Rehabilitation. Reproductive issues. Long-term morbidity.
- 0062 Patient care (diagnosis through treatment) including supportive: Quality of life – diagnosis through treatment. Pain management – diagnosis through treatment. Symptom management including nausea, vomiting, lymphedema, neuropathies, etc. Prevention of treatment-related toxicities and sequelae including symptom management, prevention of mucosities, prevention of cardiotoxicities, etc.
- 0063 Surveillance: Epidemiology and End Results (SEER) Reporting. Surveillance of cancer risk factors such as diet, body weight, physical activity, sun exposure, and tobacco use. Analysis of variations in risk factor exposure by demographic or other factors. Registries that track incidence, morbidity, and/or mortality related to cancer. Trends in use of interventional strategies. Method development for risk factor surveillance.
- 0064 Behavior related to cancer control: Behavior medicine research and interventions. Influence of social factors, such as community, policy, education, and legislation, on behaviors related to cancer control. Attitudes and belief systems and their influence on psychological health and on behaviors related to cancer control. For example, how beliefs can alter attempts to seek screening, detection, and treatment. Interventions to change attitudes and beliefs that affect behavior related to cancer control and cancer outcomes. Influences of attitudes and beliefs on compliance to treatment and prevention protocols. Psychological or educational interventions to promote behaviors that lessen treatment-related morbidity and promote psychological adjustment to the diagnosis of cancer and to treatment effects. Burden of cancer on family members and psychological/behavior issues.
- 0065 Cost analyses and health care delivery: Analyses of cost effectiveness of methods used in cancer prevention, detection, diagnosis, prognosis, treatment, and survivor care/support. Studies of providers, such as geographical or care-setting variations in outcomes. Affect of reimbursement and/or insurance on cancer control, outcomes, and survivorship support. Access to care issues.
- 0066 Education and communication: Development of communication tools and methods. Education of patients, physicians, at risk populations, and the general population about cancer. Communication to patients regarding therapeutic options. Educational interventions to promote self-care and symptom management. Communicating cancer risk to underserved populations, at risk populations, and the general public. Alternative teaching methods to communicate therapeutic options and risk reduction behavior to patients or the general public. Communication of lifestyle models that reduce cancer risk such as communication of nutrition interventions. Communicating smoking and tobacco cessation interventions. Special approaches and considerations for underserved and at risk populations. Education, information, prevention/screening assessment systems for the general public or primary care professionals. Training, predictive cancer models, pain management, and surveillance systems for primary care professionals, telehealth/telemedicine applications. Communication regarding cancer genetics, managed oncology care, communicating with survivors. Barriers to successful health communication.

Common Scientific Outline (For questions 40 and 41) - continued

- 0067 End of life care: End of life care issues including palliative care, psychological interventions with families at end of life, hospice care, pain management for terminally ill patients, etc.
- 0068 Ethics and confidentiality in cancer research: Informed consent modeling and development. Quality of Institutional Review Boards (IRBs). Protecting patient confidentiality and privacy. Research ethics.
- 0069 Complimentary and alternative approaches for supportive care of patients and survivors: Hypnotherapy, relaxation, transcendental meditation, imagery, spiritual healing, massage and biofeedback, etc.
- 0611 Resources and infrastructure related to cancer control, survivorship, and outcomes research: Informatics and informatics networks. Clinical trial groups. Statistical methodology or biostatistical methods. Surveillance infrastructures.

Scientific Model Systems

- 0071 Development of model systems: Development of model systems, including but not limited to computer-simulation model systems. *In vitro* model systems. Cell culture model systems. Organ and tissue model systems. Animal model systems such as drosophila and *C. elegans*, zebra, fish, mouse, etc.
- 0072 Characterization of model systems: Characterization of model systems, including but not limited to computer-simulation model systems. *In vitro* model systems. Cell culture model systems. Organ and tissue model systems. Animal model systems such as drosophila and *C. elegans*, zebra, fish, mouse, etc.
- 0073 Resources and infrastructure related to scientific model systems: Models made available for distribution to the scientific community.

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Appendix D

Sample Statements of Work

JONES, R.E.

Statement of Work

Development of Peptide Inhibitors of the “Cancer” Receptor (CR)

- 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):
- a. Develop a series of plasmids for expressing the CR open reading frame (Months 1-7).
 - b. Perform assays to ascertain which fragments of CR block DNA-binding (Months 7-18).
 - c. Confirm that fragments of the CR open reading frame that block DNA-binding activity also inhibit CR function *in vivo* (Months 18-24).
- Task 2.* To identify short peptides modeled after the receptor that act as inhibitors of DNA binding and subunit association (Months 18-36):
- a. Obtain synthetic CR peptides (Months 18-21).
 - b. Test the effect of synthetic peptides on the DNA-binding activity of CR (Months 20-24).
 - c. Characterize the inhibitory potency of active peptides and attempt to optimize the effect by testing additional overlapping peptides (Months 21-36).
 - d. Perform feasibility experiments to assess the ability of selected peptides to inhibit CR function in cultured cells (Months 20-36).

WILSON, JOHN R.

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 multimodal scanning configuration.
- c. Design of final optics.

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

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

YOUNG, SUSAN D.

Statement of Work

Follow-up Care for Men and Women with Cancer

Task 1. Develop Plan for Follow-up Patient Interviews, Months 1-3:

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

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

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

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

- a. Patients enrolled in our previous study will be recruited for the proposed follow-up study.
- b. Interviews subsequent to the first follow-up will be modified as necessary to reflect issues relevant to patients beyond the period of adjuvant therapy.
- c. Surveys will be sent to and data collected from enrolled patients every 6 months.

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

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

Task 5. Interim Analyses, Months 24-44:

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

Task 6. Final Analyses and Report Writing, Months 44-48:

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

Appendix E

Biographical Sketches

Provide the following information for the key personnel listed on page 1 of the Detailed Cost Estimate form (see Appendix F) 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
<p>RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds two pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.</p>			

Appendix E

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

Appendix E

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

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Appendix F

Detailed Cost Estimate Form Instructions

The following sections describe the categories of costs that should be recorded on the Detailed Cost Estimate form. All amounts entered should be in U.S. dollars.

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1. Personnel

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

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

- **Role on Project:** Identify the role of each individual listed on the project. Describe their specific functions in the “Justification” section (page 3 of the Detailed Cost Estimate form).
- **Type of Appointment (Months):** List the number of months per year reflected in an individual’s contractual appointment with the offering organization. The Department of Defense (DOD) staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent, note this with an asterisk (*) and provide a full explanation in the “Justification” section (page 3 of the Detailed Cost Estimate 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.
- **Percentage of Effort on Project:** For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.
- **Salary Requested:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual’s institutional base salary by the percentage of effort on the project.

- **Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors. A copy of the rate agreement or other documentation to support the fringe benefits should be provided.
- **Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.

2. Consultant Costs

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

3. Major Equipment

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

4. Materials, Supplies, and Consumables

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

5. Travel Costs

List the number of trips, destinations, and purposes for all proposed travel. Estimate round-trip travel fare and per diem costs for each trip. Travel to scientific meetings requires identification of the meeting and purpose. The amount allotted for travel is \$1,800 per year per PI. Itemize travel requests and justify time in the “Justification” section (page 3 of the Detailed Cost Estimate form).

6. Research-Related Patient Costs

Itemize costs of patient participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The U.S. Army Medical Research and Materiel Command will not provide funds for ongoing medical care costs that are not related to a subject’s participation in the research study.

7. Other Expenses

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

8. Consortium Costs

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

- a. The identification of the type of award to be used (e.g., cost reimbursement and fixed price);
- b. 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;
- c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- d. The proposed acquisition price.

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

The current rates, base(s), and periods to which the indirect rates apply should be provided. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

10. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form)

Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section (page 3 of the Detailed Cost Estimate form). **Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. Also, explain any escalations of the budget from the initial to the future year(s) of support.** All amounts should be in U.S. dollars. Total costs for the entire proposed period of support on the last line of page 2 should agree with the amount entered in item 4 of the Proposal Cover Booklet (Bubble Sheet) (see Appendix C).

11. Justification (third page of the Detailed Cost Estimate form)

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

Detailed Cost Estimate Form

Name of Principal Investigator (*last, first, middle*)

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

Name of Principal Investigator (*last, first, middle*)

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

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

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

Appendix G

Certificate of Environmental Compliance

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

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

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

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 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, and
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 Grants Officer.

Name of Official Responsible for
Environmental Compliance

Signature

Title

Date

Name of Organization

Appendix H

Research Involving Human Subjects and/or Anatomical Substances

Appendix H of this Program Announcement contains the required approvals, forms, and descriptions for research involving human subjects and/or human anatomical substances (including human organs, tissues, cells, body fluids from human subjects as well as graphic, written, or recorded information derived from human subjects). Specific guidelines are subject to change as governing regulations, policies, and procedures are updated. Consult “Guidelines for Research Involving Human Subjects and/or Anatomical Substances” at <http://mrmc-www.army.mil/rcq/hspd.htm> for additional information and updates.

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Research Involving Human Subjects and/or Anatomical Substances

1. Introduction

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

2. Definitions

2-a. Research

In the Common Federal Rule, “research” is defined as “...a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge” (32 CFR 219.102). Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The FDA defines “clinical investigation” as “...any experiment in which a drug is administered or dispensed to, or used involving one or more human subjects...” (21 CFR 312.3). This definition applies to research involving the use of FDA-regulated products.

2-b. Human Subjects

In the Common Federal Rule, “human subject” is defined as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information” (32 CFR 219.102). This regulation applies to the use of human organs, tissues, cells, or body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

The FDA defines “human subject” as “a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.” (21 CFR 312.3).

3. Human Subjects Research Review Board

3-a. Review Levels

In addition to first level of review and approval by the local Institutional Review Board (IRB), the OTSG requires a second level of review and approval by its Human Subjects Research Review Board (HSRRB) of all research funded by the U.S. Army involving human subjects. HSRRB approval must be obtained prior to initiation of the research protocol.

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

If your research proposal is recommended for funding and the research involves human subjects, it will determined whether your research is:

1. exempt from HSRRB review,
2. eligible for expedited review,
3. no greater than minimal risk and therefore can be administratively reviewed and approved by the Acting Chair, HSRRB, or
4. greater than minimal risk and therefore requires full HSRRB committee review.

3-b. Timelines and Outcomes

Research protocols that pose greater than minimal risk to subjects are submitted after local IRB approval through the Human Subjects Protection Branch to the HSRRB for full committee review and approval prior to implementation of the study. Review and approval by the HSRRB is usually accomplished within 45-90 days after submission of the protocol to the HSRRB. After the protocol is approved, any revisions to the protocol consent form, advertisements, questionnaires, or other related study documentation must be submitted through the local IRB to the HSRRB for approval prior to implementation. The Surgeon General of the U.S. Army must approve the recommendations of the HSRRB. The HSRRB will make one of the following four recommendations to The Surgeon General:

1. approval without revisions,
2. conditional approval contingent upon revisions and/or additional information,
3. deferral due to substantive concerns about the conduct of the protocol and/or safety of the subjects, or
4. disapproval.

4. Claim of Exempt Research

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

Certain categories of research are exempt from review by the HSRRB in accordance with federal guidelines. If your research fits in one or more of these categories, you may request exempt status for your protocol. Your protocol and Claim of Exemption form will be reviewed to evaluate your claim of exemption.

4-b. Exempt Categories

The following list taken from 32 CFR 219.101 details the exemption categories:

1. “Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if:
 - a. the human subjects are elected or appointed public officials or candidates for public office, or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - a. public benefit or service programs,
 - b. procedures for obtaining benefits or services under those programs,
 - c. possible changes in or alternatives to those programs or procedures, or
 - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies,
 - a. if wholesome foods without additives are consumed, or
 - b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.”

4-c. Claiming Exemption

Complete the form in Section 10 of this appendix entitled, “Claim of Exemption from Review by the Human Subjects Research Review Board” to claim exemption for research involving human subjects or anatomical substances.

5. Guidelines for Writing Research Protocols Involving Human Subjects

5-a. Protocol and Protocol Amendment(s)

Before writing the research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-funded research. Title 10 United States Code 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless: (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.” Furthermore and consistent with the Common Federal Rule for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual’s legally authorized representative must be obtained prior to the individual’s participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, and minors) may not be enrolled in DOD-funded research unless the research is intended to benefit each subject

enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Proposers should be aware that this law makes placebo-controlled clinical trials problematic because of the ‘intent to benefit’ requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

Investigational New Drug (IND) or Investigational Device Exemption (IDE) protocols will follow the format described in the International Conference on Harmonisation (ICH), Consolidated Guideline E6 (<http://www.ifpma.org/pdfifpma/e6.pdf>). Other protocols may follow the ICH Guideline and include applicable paragraphs.

All protocols, to include IND or IDE protocols, must include at a minimum:

1. Project Title. The consent form title must match the project title.
2. Phase. For Food, Drug, and Cosmetic Act regulated medical products, designate as a Phase I, II, III, or IV protocol.
3. Principal Investigator (PI). State the complete name, address, and phone number of the PI. Include a copy of the PI’s curriculum vitae (CV) with the protocol.
4. Location of Study. List all centers, clinics, or laboratories where the study is to be carried out. State the complete address and name of the investigator(s) for each site.
5. Time Required to Complete. State the month and year of expected start and completion times.
6. Objectives. Provide a detailed description of the purpose and objectives of the study.
7. Study Population.
 - a. Describe the source, number, age range, and gender of subjects together with the inclusion and exclusion criteria.
 - b. If pregnant subjects will be excluded from participation in the study, the method of determining pregnancy status in women of childbearing potential must be specified. Also, the time that will elapse between the pregnancy test and exposure to research procedures or medical products must be documented. For IND studies, pregnancy testing is required within 48 hours before the start of the study.
8. Protocol Design. Outline the proposed methodology in sufficient detail to show a clear course of action. Technological reliability and validity of procedures should be indicated. Minimum guidance for the plan should include:
 - a. Subject identification (describe code system to be used).

- b. Subject assignment (randomization).
 - c. Evaluations prior to entry.
 - d. Evaluations to be made during the conduct of the study (i.e., laboratory evaluations, specimens to be collected, schedule and amounts, storage to include where and whether special conditions are required, labeling, and disposition).
 - e. Clinical assessments (i.e., schedule of clinical evaluations and follow-up procedures).
9. Risk/Benefits Assessment. Describe the risks associated with the research, precautions to be taken to minimize and/or eliminate risks, and special medical or nursing care that will be needed. Describe benefits of the research to the subject. If there are no benefits, state as such.
10. Reporting of serious and unexpected adverse events.
- a. Include a definition for what constitutes an adverse event in the study.
 - (1) For IND or IDE research, include definitions as described in 21 CFR 312.32.
 - (2) All research protocols must address the following requirements:

An adverse event temporally related to participation in the study should be documented whether or not considered to be related to the test article. This definition includes intercurrent illnesses and injuries and exacerbations of preexisting conditions. Include the following in all IND safety reports: Subject identification number and initials; associate investigator's name and name of Medical Facility or Military Treatment Facility; subject's date of birth, gender, and ethnicity; test article and dates of administration; signs/symptoms and severity; date of onset; date of resolution or death; relationship to the study drug; action taken; concomitant medication(s) including dose, route and duration of treatment, and date of last dose.

- b. Describe agencies or offices to be notified in the event of a serious and unexpected adverse event. For IND or IDE studies include at a minimum, the following information about reporting serious and unexpected adverse events:

Adverse experiences that are both serious and unexpected must be reported immediately by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality 301-619-2165 and information faxed to 301-619-7803. A written report must follow the initial telephone call within 3 working days. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

- c. Include in adverse event reports the name of the person submitting the report if different from the PI, name of the study, the HSRRB log number (A-xxxx) assigned to the study, the number of subjects enrolled to date, and the number and type of serious and unexpected adverse events previously reported in the study.
 - d. In addition to the initial report of the adverse event, the report of the medical monitor and a follow-up report describing the resolution of the adverse event need to be provided.
11. Description of Protocol Drug(s) or Devices(s). If the protocol uses an investigational drug or device, provide the following information:
- a. IND/IDE number and name of sponsor.
 - b. Complete names and composition of all medication(s), device(s), or placebo(s).
 - c. Source of medication(s), device(s), or placebo(s).
 - d. Location of storage for study medication(s).
 - e. Dose range, schedule, and administration of test articles.
 - f. Washout period, if used, should be described in detail.
 - g. Duration of drug or device treatment.
 - h. Concomitant medications allowed.
 - i. Antidotes and treatments available.
 - j. Disposition of unused drug.
 - k. The procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 312.
 - l. In addition to the above list of requirements to address in the protocol, include the following with the protocol submission:
 - (1) A copy of the Investigator's Brochure and/or device manual and associated case report/data collection forms.
 - (2) For Investigational Devices, include your local IRB's assessment of the risk of the investigational device you plan to use in your study. If the device poses significant risk to research subjects, specify the IDE number obtained from the FDA, the name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 812.

12. Disposition of Data. Describe where data will be stored and duration of storage. Note that records of IND studies must be kept until 2 years after a New Drug Application is approved/ issued, or for 2 years after the IND is withdrawn. Records required for IDE studies should be retained for 2 years after the later of the following dates: the date that investigation is terminated or completed and the date that records are no longer required for support of the premarket approval application.
13. Modification of the Protocol. Describe the procedures to be followed if the protocol is to be modified.
14. Departure from the Protocol. Describe procedures and notifications to be made in the event of deviations from the approved protocol requirements.
15. Roles and Responsibilities of Study Personnel. Briefly describe the duties of study personnel. Include the name of the medical monitor. Duties of the medical monitor are as follows:

A medical monitor must be assigned to greater than minimal risk protocols. The name and CV of the medical monitor, who is someone other than the PI, must be provided. This individual should be a qualified physician who is not associated with the protocol, able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and able to monitor subjects during the conduct of the study. The medical monitor is required to review all serious and unexpected adverse events associated with the protocol and provide an unbiased written report of the event within 10 calendar days of the initial report. At a minimum, the medical monitor should comment on the outcomes of the adverse event and the relationship of the event to the test article. The medical monitor should also indicate whether he/she concurs with the details of the report provided by the PI.

The medical monitor must forward reports to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

16. Investigators conducting greater than minimal risk research must include the following description of requirements of the Volunteer Registry Database in the consent form:

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

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

If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the local IRB-approved advertisement must be provided.

For studies involving investigational drugs or devices, local IRB review of advertisements is necessary to ensure that the information is not misleading to the subjects participating in IND or IDE studies. The FDA has established guidelines on advertisements for subjects. General guidance includes: name and address of PI, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.

5-c. Surveys, Questionnaires, or Other Instruments

If the research involves surveys, questionnaires, or other instruments, include a copy of each of these documents with the protocol submission.

6. Informed Consent Requirements

6-a. Elements of Informed Consent

The following information is essential for informed consent documents (32 CFR 219.116 and AR 70-25):

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

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 PI before you enroll in this study.

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

- a. The proposed recipient may absorb such costs into the institution's operating budget.
 - b. The proposed recipient's liability insurance, if available, may be sufficient to cover any medical care costs. The proposed recipient's business office and/or legal advisor must ensure that there is adequate coverage under this liability insurance.
 - c. The proposed recipient could negotiate an additional amount of funds, if available, into the award that will cover such medical care cost (such as liability insurance).
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

6-b. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject (32 CFR 219.116 and applicable state/local laws):

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

7. Documentation of consent for HIV antibody testing, if scheduled, may be addressed in the body of the consent form or as a separate HIV test consent form. Documentation should address any notifications required by local laws as well as any specific issues regarding confidentiality of positive test results.

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

6-c.i. Certification of Translation

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

6-c.ii. Sample Donation

If the samples donated in this study will be used in other studies, the following statement should be included in the consent form.

“During this study, you will be asked to provide _____ (clearly specify the type of samples to be provided). These samples will be used for _____ (enter all known and anticipated uses) and may also be used for purposes that are currently unknown. There is a chance that the samples that you are donating under this study may be used in other research studies and may have some commercial value. (If a commercial value is anticipated, that value should be clearly described at this point). Should your donated sample(s) lead to the development of a commercial product, _____ will own it and may take action to patent and license the product. _____ does not intend to provide you with any compensation for your participation in this study nor for any future value that the sample you have given may be found to have. You will not receive any notice of future uses of the sample(s). (When the study involves treatment as well as research, the following language should be added: ‘You may agree to participate in the research protocol, but refuse to provide the additional samples discussed above.’).”

In addition, a donation form may be prepared for signature by the volunteer and a witness that states, “As a participant in _____ (insert the title of the study), I voluntarily donate any and all _____ (clearly specify the type of sample(s) to be provided) to _____. These samples will be used for (enter all known and anticipated uses) and may also be used by _____ for uses not currently known to me. There is a possibility that the samples that I am donating under this study may be used in other research studies and may have some commercial value. (If a commercial value is anticipated, that value should be clearly described at this point). Should my donated sample(s) lead to the development of a commercial product, _____ will own it and it is possible that it will be patented and licensed by _____. _____ does not intend to provide me any compensation for this and will not give me any notice of future uses of my sample(s).”

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

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

6-c.iv. Confidentiality: Military Personnel

The following statement must be included in the consent form for all protocols that enroll 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 to subjects, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

6-c.v. Pregnant Women

If pregnant women will be excluded, the following statement must be included if pregnancy during or after the study constitutes a risk to the participant or fetus:

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

6-c.vi. Volunteer Registry Database

For all studies involving greater than minimal risk, notification regarding the requirements of the Volunteer Registry Database must be included in the consent form. The U.S. Army Medical Research and Development Command Form 60-R must be completed for each volunteer. Send all completed forms to the Human Subjects Protection Branch annually and at the completion of the study. An example of the form is located in Section 12 of this appendix.

The following statement is normally included in the “Confidentiality” section of the consent form:

It is the policy of the USAMRMC that data sheets be completed on all volunteers participating in research for entry into this Command’s Volunteer Registry Database. The information to be entered into this confidential database includes name, address, social security number, study name, and dates. The intent of the database is twofold: first, to readily answer questions concerning an individual’s participation in research sponsored by the USAMRMC and second, to ensure that the USAMRMC can exercise

its obligation to ensure that research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at the USAMRMC for a minimum of 75 years.

7. Assurances

If an institution has a current Multiple Project Assurance (MPA) with the DHHS Office for Protection from Research Risks (OPRR), submit a letter with the following protocol information: (a) MPA number, (b) risk level that the IRB classified the protocol (no greater than minimal risk or greater than minimal risk), (c) date of IRB approval, and (d) next continuing review date. This letter must be on letterhead stationery and signed by the Chairperson of the IRB that approved the protocol.

If the institution does not have a current MPA with OPRR, a written Assurance of Compliance must be filed with the Human Subjects Protection Branch of the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality. The obligation to obtain an assurance can be found in 32 CFR 219.103.

There are four requirements for a DOD Single Project Assurance (SPA) that must be submitted to the Human Subjects Protection Branch. The first is to complete a DOD SPA application. This application can be found at <http://mrmc-www.army.mil/rcq/hspd>

The second requirement is to provide a table of the IRB membership with the credentials (e.g., M.D., Ph.D.) of each member, affiliation with the institute, and the role fulfilled on the IRB (e.g., chairperson, alternate, scientist). An example of this table is provided in the SPA application.

The third requirement is to provide short CVs or biographical sketches of all IRB members. These CVs are used to verify qualifications of the IRB members. The last requirement is to provide the written procedures that are used by the IRB as outlined in 32 CFR 219.103. The SPA number will be issued after the protocol is approved by the HSRRB.

The fourth requirement is to obtain a letter on letterhead stationery from the Chairperson of the IRB that approved the protocol that must accompany the SPA application. The risk level assigned to the protocol by the IRB must be included along with the date of approval by the IRB and the next continuing review date.

8. Inclusion of Women and Minorities in Research

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

9. Where to Go for Help and Information

If your research involves human subjects, you should first contact your local IRB for institutional requirements. If you have questions regarding the USAMRMC protocol and consent form requirements or the review and approval process, contact the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Branch at the address or phone number listed below.

Phone: 301-619-2166/2165

Mail: Commander

U.S. Army Medical Research and Materiel Command

ATTN: MCMR-RCQ-HR

504 Scott Street

Fort Detrick, MD 21702-5012

References:

- Title 32 Code of Federal Regulations, Part 219, Protection of Human Subjects
- Title 21 Code of Federal Regulations, Part 50, Protection of Human Subjects
- Title 21 Code of Federal Regulations, Part 56, Institutional Review Boards
- Title 21 Code of Federal Regulations, Part 312, Investigational New Drug Application
- Title 21 Code of Federal Regulations, Part 812, Investigational Devices
- Title 45 Code of Federal Regulations, Part 46, Subparts B,C, and D, Protection of Human Subjects
- Code of Federal Regulations is located at <http://www.access.gpo.gov/nara/cfr/index.html>
- Army Regulation 70-25, Use of Volunteers as Research Subjects
- Army Regulation 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances
- Army Regulations can be located at <http://www.usapa.army.mil/gils/epubs1.html>
- Office of The Surgeon General Regulation 15-2, Human Subjects Research Review Board
- Title 10 United States Code, Section 980
- Title 24 United States Code, Section 30
- Department of Defense Directive 3216.2
- International Conference on Harmonisation, Good Clinical Practice, Consolidated Guideline
- is located at <http://www.ifpma.org/pdfifpma/e6.pdf>; for all other guidelines, access the ICH homepage at <http://www.ifpma.org/ich1>

Appendix H

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

U.S. Government Printing Office:

Phone: 202-512-1800
E-mail: www.access.gpo.gov/su_docs
Mail: Superintendent of Documents
P.O. Box 371954
Pittsburgh, PA 15250-7954

National Technical Information Services:

Phone: 703-605-6000; 800-553-NTIS
E-mail: orders@ntis.fedworld.gov
Mail: National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161

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

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR'S NAME:	PROPOSAL NO:
INSTITUTION:	

1. Will existing or archived data, documents, medical records, or database records be used? Yes No

2. Will biological specimens (e.g., cells, tissues, blood) be used? Yes No

3. Indicate below the sources of existing or archived data or biological specimens or cell lines (e.g., cell lines purchased from ATCC).

4. Will the donors of the original biological specimens be able to be identified, directly or indirectly, through identifiers linked to the donor? Yes No

5. Will data be recorded in writing? Yes No

6. Will data be recorded by audiotape? Yes No

7. Will data be recorded by videotape? Yes No

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

9. Will subjects be identifiable either by name or through demographic data? Yes No

If the answer to any question 4–9 is yes, describe on a separate sheet of paper how the confidentiality of a subject's identity will be maintained. Also describe plans for maintaining or destroying identifying links to subjects after the protocol has been completed.

Principal Investigator's Signature

Date

11. Protocol Submission Checklist (Complete the following checklist and submit with your proposal application.)

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR'S NAME:	PROPOSAL NO:
INSTITUTION:	

All Protocols:

- Consent Form(s)
- If potential commercial use of sample(s) or future use of sample(s) in other studies, a Sample Donation consent form is required.
- With HIV testing, documentation of consent for HIV antibody testing, if scheduled, may be addressed in the body of the consent form or as separate HIV test consent form.
- Protocol
- Curriculum Vitae or Biographical Sketch for Principal Investigator and Medical Monitor
- Scientific Review/Peer Review Approval(s)
- Letter from the IRB Chairperson with the following protocol information: (a) MPA number, (b) risk level that the IRB classified the protocol, (c) date of IRB approval, and (d) next continuing review date
- Copy of Recruitment Advertisement(s) and/or Poster(s)

Investigational New Drug (IND) Protocols – additional requirements:

- Document Specifying IND Number
- Investigator's Brochure
- Copy of Case Report Forms (blank)

Medical Device Protocols – additional requirements:

- Document from manufacturer declaring level of risk for device (nonsignificant risk or significant risk) and IDE form
- Document Specifying IDE Number
- Manufacturer's Device Manual/Device Information

Protocol Submission Checklist (cont.)

What type of study is proposed?

- Phase I Clinical Trial Survey/Medical Record Review Community Intervention
- Phase II Clinical Trial Cohort (longitudinal study) Laboratory Experiment
- Phase III Clinical Trial Retrospective (case-control) Tissue Only
- Multicenter Trial Program/Policy Study Qualitative Study
- Pilot Study Cross-Sectional (prevalence) Other: _____

Check all procedures applicable to this protocol:

- Experimental Drug/Medications IND# _____ Prosthetic Orthopedic Devices
- Marketed Agent, but Unapproved Use IND# _____ Nutrition/Metabolism Study
- Experimental Device, IDE# _____ Tissue/Organ Transplant
- Immunological Study Radiation or Radioactive Material
- Artificial Organ Study Human Embryos
- Experimental Treatments Diagnostic Procedures
- Experimental Surgery Anatomical Substances/
Biological Specimens

Other: _____

Drug(s) to be used: _____ Drug Type* _____

*Drug Type may be chosen from the following list or other type may be stated as appropriate:

- | | | | |
|----------------------------------|-------------------------|-----------------------------|----------------------------------|
| Analgesics | Anti-cancer drugs | Cardiac drugs | Hematologic agents |
| Anesthetics | Anti-convulsants | Diuretics | Hormones |
| Anti-allergy drugs | Anti-hypertensive drugs | Drugs affecting respiration | Tranquilizers/psychotropic drugs |
| Anti-arrhythmic drugs | Anti-Parkinson agents | Eye/Optical drugs | Vitamins/Minerals |
| Antibiotics/anti-infective agent | Autonomic drugs | Gastro-intestinal drugs | |

Human Subject Information:

Age range of subjects: _____.

Number of subjects expected to be enrolled: Total number of subjects locally _____.

If multicenter study, total number of subjects at all centers _____.

- Subject Gender: Male Female Both Non-Consenting Subjects
- Subject Age: Infant Child Adolescent Adult Geriatric
- Vulnerable Subject Class: Prisoners Minorities HIV + Psychologically Impaired
- Subject Recruitment: In-Patients Out-Patients Paid Volunteers Students/Employees

Principal Investigator's Signature

Date

VOLUNTEER REGISTRY DATA SHEET (USAMRDC 60-R) (continued)

PART C - ADDITIONAL INFORMATION

(To Be Completed by Investigator)

PLEASE PRINT, USING INK OR BALLPOINT PEN

16. Location of Study: _____

17. Is Study Completed: Y:___ N:___

Did volunteer finish participation: Y:___ N:___ If YES, date finished ___/___/___
DD MM YY

If NO, date withdrawn: ___/___/___ Reason Withdrawn: _____
DD MM YY

18. Did any Serious or Unexpected Adverse Incident or Reaction Occur: Y:___ N:___ If YES, Explain:

19. *Volunteer Follow-up: _____

Purpose: _____

Date: ___/___/___ Was contact made: Y:___ N:___ If NO action taken, explain: _____
DD MM YY

20. *Hard Copy Records Retired: Place: _____ File NR: _____

21. *Product Information:

Product: _____

Manufacturer: _____

Lot #: _____ Expiration Date: _____

NDA # _____ IND/IDE #: _____

*Indicates that item may be left blank if information is unavailable or does not apply. Entries must be made for all other items.

When completed, a copy of this form should be sent to the address below:

**Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-HR
Fort Detrick, MD 21702-5012**

Appendix I

Research Involving Animals

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Research Involving Animals

1. Introduction

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

The Department of Defense (DOD) definition of **animal: Any live nonhuman vertebrate.**

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

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

2. Alternatives to Painful Procedures

A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied. A written narrative description of the methods and sources used to search for alternatives to painful procedures, including those procedures in which pain is alleviated, **must** be provided. The minimal written narrative must include the databases searched or other sources consulted, the date of the search and the years covered by the search, and the key words and/or search strategy used. Where federal law requires specific testing procedures, state the appropriate Code of Federal Regulations or legal guidance that requires this testing. (The U.S. Army Medical Research and Materiel Command [USAMRMC] reserves the right to request evidence that a literature search for alternatives to painful procedures was performed.)

3. Rationale for Using Animals

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

4. Species Identification and Rationale

Identify the species of animals to be used and provide a rationale for their use. Explain why this particular animal model(s) was chosen over other animal models. Include references to unique biologic or physiologic characteristics that influenced the choice of animal model(s).

5. Rationale for the Number of Animals Required

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

6. Experimental Design

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

7. Anesthesia/Analgesia/Tranquilization

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

8. Study Endpoint

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

9. Euthanasia or Final Disposition

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

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

Provide written documentation of protocol approval from the Institutional Animal Care and Use Committee(s) (IACUC) where the animal research will be performed including any subcontracting facility. If IACUC approval is pending, provide a statement to this effect. Evidence of committee review can follow proposal submission, but must be provided prior to award. **RESEARCH WILL NOT BE FUNDED WITHOUT EVIDENCE OF APPROVAL FROM THE IACUC(s).**

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

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

12. Qualifications

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

13. Accreditation

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

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

14. Principal Investigator Assurances

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

1. I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and/or tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.
2. I assure that the animals authorized for use in this protocol will be used only in the activities, manner, and quantities described herein, unless a deviation is specifically approved by my IACUC and the USAMRMC Animal Care and Use Review Office.
3. I accept full responsibility for the proper care and use of the animals during the conduct of research outlined in the proposal.
4. I verify that I have made a reasonably good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
5. I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent in those procedures and have received training on the use of animals in research as required by the Animal Welfare Act of 1985.
6. I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal and that the minimum number of animals needed for scientific validity will be used.

Principal Investigator's Signature

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

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Appendix J

Safety Program Plan

Appendix J of this Program Announcement contains the required assurances, approvals, forms, and descriptions relating to safety in the research environment.

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Safety Program Plan

Each of the applicable items below must be addressed in a proposal appendix entitled “Safety Program Plan” and must be prepared specifically for the proposal. Each item should be research specific and addressed in order. Institutional safety manuals may be referenced; however, **do not send copies of your Safety Manual or Standard Operating Procedures (SOPs)**. A list of program contents with a brief description of each item (maximum three pages) is acceptable. Provide a web site address, if available, for additional safety information.

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

1. Research Operations/SOPs

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

2. Facility Equipment and Description

This section should include a description of any safety cabinets and ventilation system employed.

3. Hazard Analysis

Provide a description of each hazard identified, the hazard analysis performed based on maximum credible event, and the plan to minimize or eliminate each hazard.

4. Radioactive Materials

Identify any radioactive materials used and the disposal method for each. A copy of the Nuclear Regulatory Committee or state-approved license shall be submitted with this application.

5. Recombinant DNA

Research involving recombinant DNA must meet or exceed National Institute of Health (NIH) “Guidelines for Research Involving Recombinant DNA Molecules,” January 1997 edition. Include a written approval letter from the organization’s Institutional Biosafety Committee. If DNA experiments are exempt under the NIH Guidelines, include a copy of the written exemption notification.

Copies of the above NIH Guidelines are available at:

Phone: 301-496-9838
Fax: 301-496-9839
Web site: www.nih.gov/od/oba
Mail: Office of Biotechnology Activities
National Institutes of Health, MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda, MD 20892-7010

6. Biological Defense Program Requirements

Contractors performing work with **Biosafety Level-3 and/or -4** material must prepare a safety plan in accordance with 32 CFR 626.18. See www.access.gpo.gov/nara/cfr/index.html for a copy of the 32 CFR.

The principal investigator (PI) is directly responsible and liable for all aspects of research project safety and ensures that all Safety Plan requirements are in compliance with 32 CFR 626 and 627 (Biological Defense Safety Program and The Biological Defense Safety Program, Technical Safety Requirements).

Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of Biological Defense Program (BDP) activities and the appropriate support necessary, to include any equipment and training needed to provide effective emergency response. Agreements with external agencies must be formalized. (For the purpose of this requirement, the term “local emergency support agencies” refers to any agency that could reasonably be expected to have some capability to provide timely and effective support in the management or resolution of a biological mishap arising from BDP operations.)

A copy of this agreement must be submitted with the proposal.

Local Emergency Support (Sample Form)

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

Acknowledged:

Name	Title (e.g., Fire Chief)	Date
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7. Institutional Safety Director/Manager Assurances

- I assure that this institution has an existing institutional safety and occupational health program that meets appropriate federal, state, and local regulations as required by the U.S. Army Medical Research and Materiel Command Safety Office.
- I assure that all hazards described in the proposal have been identified, eliminated, and/or controlled in such a manner to provide for a safe research laboratory environment.

Safety Director/Manager Signature

Date

8. Principal Investigator Assurances

The PI must provide the following signed assurances.

- I assure that my institution has an existing safety and occupational health program that meets appropriate federal, state, and local regulations as required by the Occupational Safety and Health Act; that hazards have been identified, eliminated, and/or controlled; and that research may be performed safely under laboratory conditions.
- I assure that I shall adhere to the institutional safety and occupational health program policies and procedures.
- I assure that I will supervise the performance of my laboratory staff to ensure that the required safety practices and techniques are employed.
- I assure that I have involved the institutional safety officer in the planning of this research proposal, discussing all aspects of the proposal that relate to occupational health and safety.
- I understand that I am directly responsible and liable for all aspects of safety and occupational health specific to my research protocol.

Principal Investigator Signature

Date

Appendix K

General Information

Appendix K of this Program Announcement contains general information relating to U.S. Army Medical Research and Materiel Command (USAMRMC) policies and procedures.

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General Information

1. U.S. Army Medical Research and Materiel Command 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 (PI) should submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institute, commercial firm, or Government agency (including military laboratories) in order to receive support.

2. Procurement Integrity, Conflicts of Interest, and Other Improper Business Activities

The Procurement Integrity Act, Title 41 U.S. 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.

3. Disclosure of Information outside the Government

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

4. Award Eligibility

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

5. Government Obligation

PIs are cautioned that only an appointed Contracting/Grant Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. A PI who, or an organization that, makes financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grant Officer does so at their own risk.

6. Information Service

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

7. Funding Instrument

All awards under this Program Announcement are anticipated to be grants or cooperative agreements.

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

Fax: 301-619-2937
E-mail: q&a.baa@det.amedd.army.mil
Mail: Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA
Fort Detrick, MD 21702-5014

8. Inquiry Review Panel

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

9. Equipment/Property

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

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

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Appendix L

Acronym List

AR	Army Regulation
ATCC	American Type Culture Collection
BDP	Biological Defense Program
CDMRP	Congressionally Directed Medical Research Programs
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CR	Cancer Receptor
CV	Curriculum Vitae
DHHS	Department of Health and Human Services
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOEd	Department of Education
EPI	Environmental Process Interview
FDA	Food and Drug Administration
FY	Fiscal Year
HAZCOM	Hazard Communication Standard
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HSRRB	Human Subjects Research Review Board
IACUC	Institutional Animal Care and Use Committee(s)
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IND	Investigational New Drug
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MPA	Multiple Project Assurance
N/A	Not Applicable
NCI	National Cancer Institute
NIH	National Institutes of Health
OCNIA	Ovarian Cancer New Investigator Award
OCRCP	Ovarian Cancer Research Program
OPRR	Office for Protection from Research Risks
OTSG	Office of the Surgeon General
PI	Principal Investigator
PPA	Program Project Award
RCQ	Regulatory Compliance and Quality
SEER	Surveillance Epidemiology and End Results

Appendix L

SOPs	Standard Operating Procedures
SPA	Single Project Assurance
SPORE	Specialized Program of Research Excellence
SSN	Social Security Number
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code