

Appendix A
Fiscal Year 2002 Ovarian Cancer Research Program Announcement Electronic
Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than June 4, 2002. This form can be found on the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/02ocrp1>

Appendix B

Proposal Preparation

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Proposal Preparation

1. Who May Apply

Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include 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 on specific award mechanisms for additional eligibility criteria.

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

Historically Black Colleges and Universities/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. The DOEd list is posted on the CDMRP web site at <http://cdmrp.army.mil/spp> under Minority Institutions. 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.

¹ Executive Orders 12876, 12900, and 13021

2. Proposal Acceptance Criteria

Please follow the compliance guidelines listed below when preparing your proposal. **Note that all proposals must be converted into an electronic PDF (Portable Document Format) file for electronic submission. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.**

Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner in order to assist scientific reviewers responsible for reviewing proposal merit. Scientific peer reviewers will expect to see a consistent, prescribed format for each 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. **Excess pages may result in administrative rejection prior to scientific peer review.**

For the preparation of proposals for PDF submission, 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, font size, spacing, margin, and printing guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Type Color: Black type for all graphs, diagrams, tables, and charts. The proposal should contain only material that can be photocopied. Investigators are cautioned that color graphs or photographs may not reproduce in subsequent photocopies. Therefore, submission of color figures, tables, graphs, or photographs is not recommended.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches. (Note to international applicants: The text of the proposal must not exceed 7.0 x 10.0 inches [approximately 19 cm x 25.5 cm].)

To assist applicants, the following example is included.

This illustrates the minimum font size and margins and the required line spacing; this differs from years past. This illustrates the minimum font size and margins and the required line spacing; this differs from years past. This illustrates the minimum font size and margins and the required line spacing; this differs from years past. This illustrates the minimum font size and margins and the required line spacing; this differs from years past. This illustrates the minimum font size and margins and the required line spacing; this differs from years past.

3. Duplicate Submissions

Submission of the same research project from different applicants to the FY02 OCRP will not be allowed, and all such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.

4. Proposal Information

Please complete the Proposal Information as described at <http://cdmrp.org/proposals>. Instructions will be available through the web site by May 7, 2002. See Section 6, pages iii and iv of the [Foreword](#) or [Part 21 of this Appendix](#) (Proposal Submission) for more information regarding the complete electronic submission process.

5. Title/Referral Page - No page limit

Please complete the Title/Referral Page, which can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/reposit> Complete each section as described:

- a. Proposal title (up to 160 characters).
- b. Proposal log number (this will be automatically provided when a draft of the Proposal Information is completed and saved).
- c. Applicant's full name (first, middle initial, last).
- d. Award mechanism.
- e. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, 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).

- f. 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 applicant, co-investigators, research associates, research assistants, consultants, collaborators, and subcontractors. In addition, list the names of other researchers outside the scope of this proposal that may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and role(s) on the proposed project or perceived conflicts of interest.

Title/Referral Page
No Page Limit

a. Proposal title (up to 160 characters)

--

b. Proposal log number

--

c. Applicant's full name (first, middle initial, last)

--

d. Award mechanism

--

e. Keyword descriptive technical terms

--

f. Conflicts of interest: Include the following information (no page limit)

Name	Institutional Affiliation(s)	Role(s) on Proposed Project or Perceived Conflicts of Interest

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 consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the applicant's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when a draft of the electronic Proposal Information is saved).

7. Checklist for Proposal Submission (Instructions)

The Checklist for Fiscal Year 2002 (FY02) Ovarian Cancer Research Program (OCRP) Proposal Submission found on [page B-8](#) must be completed and submitted with your PDF proposal. Place it immediately after the Table of Contents.

Complete and place this form immediately after the Table of Contents to confirm that all components are included in your application.

Checklist for FY02 OCRP Proposal Submission

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Proposal Information completed
<input type="checkbox"/>	<input type="checkbox"/>	Title/Referral Page
<input type="checkbox"/>	<input type="checkbox"/>	Table of Contents
<input type="checkbox"/>	<input type="checkbox"/>	Checklist for FY02 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 (adhere to page limits for the individual mechanism)
<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"/>	Biographical Sketches (3-page limit per individual)
<input type="checkbox"/>	<input type="checkbox"/>	Principal Investigator
<input type="checkbox"/>	<input type="checkbox"/>	Collaborating investigators and other key personnel
<input type="checkbox"/>	<input type="checkbox"/>	Existing/Pending Support (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Facilities/Equipment Description (no page limit)
		<i>Administrative Documentation:</i>
<input type="checkbox"/>	<input type="checkbox"/>	List of items included in this section
<input type="checkbox"/>	<input type="checkbox"/>	Letters of support from the applicant's institution and collaborating individuals (if applicable) (all awards)
<input type="checkbox"/>	<input type="checkbox"/>	Detailed Cost Estimate (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	Total cost estimate matches Proposal Information
<input type="checkbox"/>	<input type="checkbox"/>	Instruments (no page limit)
<input type="checkbox"/>	<input type="checkbox"/>	List of documents included in Instruments Section (all awards)
<input type="checkbox"/>	<input type="checkbox"/>	Publications and/or Patent Abstracts (5-document limit)
<input type="checkbox"/>	<input type="checkbox"/>	Certificate of Environmental Compliance
<input type="checkbox"/>	<input type="checkbox"/>	Principal Investigator Safety Program Assurance

NOTE: Exceeding page limits may result in proposal rejection prior to peer review. Submit only materials specifically requested or required in this program announcement. Submission of additional materials may be construed as an attempt to gain an unfair advantage.

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 applicant. Abstracts must be submitted as part of the proposal. **Do not include figures or tables 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 submits abstracts that fully describe the proposed work.** Sample abstracts are included in [Appendix D](#) of this program announcement.

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.

- a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- c. Specific Aims: State concisely the specific aims of the study.
- d. Study Design: Briefly describe the study design.
- e. 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 non-scientific community. It should be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. The lay abstract should not duplicate the technical abstract.

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

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

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

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

- a. Describe the work to be accomplished as tasks (tasks may relate to specific aims),
- b. Identify the timeline and milestones for the work over the period of the proposed effort,
- c. Indicate the numbers of research subjects (animal or human) for each task,
- d. Identify methods, and
- e. Identify products/deliverables for each phase of the project.

The SOW must not exceed 2 pages of single-spaced typing. Several sample SOWs are included in [Appendix D](#) of this program announcement.

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 are pertinent to one or more critical issues of the disease.

11. Proposal Body - Start section on a new page

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 included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. Each biographical sketch must not exceed 3 pages. The Biographical Sketch form can be found in [Appendix E](#) or downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/reposit>

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 applicant 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

The first item in this section must be a list of all the items in the Administrative Documentation section.

Provide letter(s) from the applicant’s institution and proposed collaborating individuals (if applicable) confirming support and collaborative efforts, respectively 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. Support documentation **will not** be accepted separately from the electronic proposal submission.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. All documents or letters requiring signatures must be signed and then scanned into the proposal prior to submission. Help lines will be available by May 7, 2002 to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic

submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (<http://cdmrp.army.mil>) and the proposal submission web site (<http://cdmrp.org/proposals>). Alternately, help can be obtained by e-mail, at help-proposals-cdmrp@cdmrp.org

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. In addition, budgets will also be reviewed during award negotiations. 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/funding/default>. The cost of preparing proposals in response to this program announcement is not considered an allowable direct charge to any resultant award.

For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See [part 7 of Appendix F](#) (Detailed Cost Estimate) for more details.

19. Instruments - No page limit

Include an appropriately titled page listing the documents you have in this section. Questionnaires, survey instruments, or clinical protocols that apply to the proposal should be included in this section.

20. Publications and/or Patent Abstracts - 5-document limit

Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, **the extra items will not be peer reviewed. Submit only material specifically requested or required in this program announcement. Submission of unrequested material may be construed as an attempt to gain a competitive advantage and will be removed.**

These documents must be incorporated into the electronic PDF version of your proposal. Help lines will be available by May 7, 2002 to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (<http://cdmrp.army.mil>) and the proposal submission web site (<http://cdmrp.org/proposals>). Alternately, help can be obtained by e-mail, at help-proposals-cdmrp@cdmrp.org

21. Proposal Submission

Electronic submission is required. No paper copy submissions will be accepted.

Proposals will be submitted electronically at <http://cdmrp.org/proposals>. The web site will be available for proposal submission by May 7, 2002. One electronic PDF version of the proposal is required and will count as the official proposal submission. The electronic PDF proposal must be uploaded/submitted through the Internet by an authorized Administrative Representative from the Sponsored Programs Office (or equivalent) of your organization no later than **11:59 p.m. (applicant's local time) June 18, 2002** and must be accompanied by the Proposal Information, as described below.

Several steps are critical for successful electronic submission of your proposal.

1. The applicant is required to submit Proposal Information (referred to in previous years as "Proposal Cover Booklet") online at <http://cdmrp.org/proposals>, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf. **The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process at least 2 weeks prior to the submission deadline.**
2. Once the applicant has submitted the Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.
3. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Applicants are encouraged to coordinate early with their Sponsored Programs Office.
4. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the CDMRP web site no later than **11:59 p.m. (applicant's local time) June 18, 2002**. Detailed instructions for electronic submissions will be available at <http://cdmrp.org/proposals>.

22. Submission Deadline

The submission deadline for all proposals requested in this program announcement is 11:59 p.m. (applicant's local time) June 18, 2002. The electronic PDF version of your proposal must

be sent through the Internet by the Sponsored Programs Office (or equivalent) of your organization by that time.

If your proposal is submitted electronically after 11:59 p.m. (applicant's local time) on June 18, 2002, it may not be considered for review.

23. Regulatory Compliance and Quality Requirements

Please complete and sign the Certificate of Environmental Compliance found on [pages B-15](#) to B-16 of this Appendix. Also, please complete and sign the Principal Investigator Safety Program Assurance Form found on [page B-17](#) of this Appendix.

The other Regulatory Compliance and Quality (RCQ) Requirements documents (Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) should not be included with the submitted proposal; instead, the applicant should only provide these documents to the USAMRMC upon request. These documents should be available on the CDMRP web site by April 2002.

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 1500-1508¹) that implement the National Environmental Policy Act (Public Law 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 (Army Regulation 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 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.

¹ Title 40, Code of Federal Regulations, Sections 1500-1508.

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

Principal Investigator Safety Program Assurance

- ◆ I assure that I have involved the Facility Safety Director/Manager in the planning of this research proposal, discussed with him/her all aspects of the proposal that relate to occupational health and safety, and will help him/her prepare the annual Facility Safety Plan Status Report.
- ◆ I assure that I will comply with my institution's safety program and its requirements.
- ◆ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.
- ◆ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.
- ◆ I assure that hazards associated with my research have been identified, eliminated and/or controlled.
- ◆ I assure that all Safety Plan requirements are in compliance with 32 CFR 626 and 627, "Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements" (*if applicable*).

Name of Principal Investigator (print)

Signature

Date

Mailing Address: _____

Street

City

State

Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____

Appendix C

Proposal Information

The Proposal Information and instructions for completing it will be available at the Congressionally Directed Medical Research Programs-related web site <http://cdmrp.org/proposals>. The web site will be available for proposal submission by May 7, 2002. One electronic PDF (Portable Document Format) version of the proposal is required and will count as the official proposal submission. Applicants should refer to sections on individual award mechanisms and [Appendix B](#) for appropriate submission requirements.

Several steps are critical for successful electronic submission of your proposal.

1. The applicant is required to submit Proposal Information (referred to in previous years as "Proposal Cover Booklet") online at <http://cdmrp.org/proposals>, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf. **The Proposal Information must be submitted prior to submission of the proposal. We encourage applicants to begin this part of the submission process at least 2 weeks prior to the submission deadline.**
2. Once the applicant has submitted the Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.
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Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. Proposal Information must be completed online and the PDF proposal uploaded/submitted through the web site (<http://cdmrp.org/proposals>) no later than **11:59 p.m. (applicant's local time) June 18, 2002 as specified on page ii of the Foreword.** Detailed instructions for electronic submissions will be available at <http://cdmrp.org/proposals> by May 7, 2002.

Appendix C

Help lines will be available by May 7, 2002 to answer specific questions regarding Proposal Information and the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (<http://cdmrp.army.mil>) and the proposal submission web site (<http://cdmrp.org/proposals>). Alternately, help can be obtained by e-mail, at help-proposals-cdmrp@cdmrp.org.

Appendix D

Sample Abstracts and Statements of Work

	<u>Page</u>
Sample Abstracts (Technical and Lay).....	D-2
Sample Statements of Work.....	D-4

TECHNICAL ABSTRACT

Low-Risk Genes for Epithelial Ovarian Cancer

Georgia Chenevix-Trench, Ph.D.

Background: Family history has consistently emerged as the highest-risk factor for ovarian cancer after age with the life-time risk for ovarian cancer increasing from 1% to 7% if one first degree relative is affected. Current methods do not allow genome-wide searches for low-risk genes, and association studies of candidate genes are considered the most powerful way to dissect complex traits. Candidate genes can be predicted from the many hypotheses put forward for the etiology of ovarian cancer, and it is likely that subtle but common variants in these genes may impact on the individual's risk of disease. The attributable risk associated with such variants would be high because of their frequency, even if the increase in risk is small. Genes of interest include those mediating a range of functions relevant to proposed theories of ovarian pathogenesis such as steroid hormone metabolism and DNA repair.

Objective/Hypothesis: Based on the etiological hypotheses, we hypothesize that low-risk ovarian cancer genes will include genes with common allelic variants that are involved in androgen and progesterone synthesis and action, and double strand DNA repair. We further hypothesize that there may be heterogeneity with respect to risk of particular histologic and molecular subtypes and propose to stratify cases by these subtypes to clarify the role of these genes.

Specific Aims:

- (1) To genotype ~1,000 ovarian cancer cases and ~1,000 controls collected in the Australian Ovarian Cancer Study (AOCS) and ~500 cases and ~800 controls from our current resources for known variants in candidate low-risk predisposition genes acting in the (a) androgen and progesterone pathways and (b) double strand DNA repair pathway.
- (2) To assess the role of these variants in epithelial ovarian cancer risk stratifying by histologic subtype and to generate new hypotheses with respect to biologic pathways for ovarian cancer stratifying by molecular subtype for the cases on which cDNA microarray analysis will be performed in Project 1.
- (3) To examine whether specific genotypes in the pathways mentioned above interact with particular ovarian cancer risk factors. In particular, we will focus on reproductive risk factors relevant to the incessant ovulation and androgen hypotheses such as lifetime ovulatory cycles, parity, oral contraceptive pill use, androgen excess, and hormone replacement therapy.

Study Design: We will carry out a case-control study using our current resource of ~500 cases from a previous case-control study carried out by our collaborators and ~800 controls from a population-based study of breast cancer carried out in Australia, as well as ~1,000 cases and 1,000 controls to be ascertained by the AOCS. Candidate genes will be chosen from the androgen and progesterone synthesis and metabolism pathways and from the double strand DNA repair pathway. Polymorphisms within these genes that are likely to have functional significance will be chosen for analysis. Analysis will then be performed using unconditional logistic regression to allow for adjustment for other risk factors. Gene-environment interactions will be assessed by conducting stratum-specific analyses and also by entering multivariate interaction terms into the logistic regression models. We will use polytomous logistic regression in order to examine associations of low-risk genes with specific histologic and molecular subtypes (identified by cDNA array analysis of most tumors from the AOCS in Project 1) and to control for potential confounding factors.

Relevance: Identification of women at elevated risk for ovarian cancer on the basis of their genotype will allow them to be targeted for screening, and for intervention studies. Furthermore, identification of low-risk genes will focus attention on particular biological pathways that will then warrant further research at the molecular and cellular level leading to a better understanding of ovarian cancer biology.

LAY ABSTRACT

Low-Risk Genes for Epithelial Ovarian Cancer

Georgia Chenevix-Trench, Ph.D.

Having a mother, sister, daughter, or aunt with ovarian cancer substantially increases a woman's risk of developing ovarian cancer herself. Some of this risk is likely to arise because these women carry genes that increase their risk by two- to threefold. The best way to identify these genes is to compare carefully chosen candidate genes that likely to play a role in ovarian cancer susceptibility in a large number of ovarian cancer cases compared with controls. Candidate genes can be predicted from the many hypotheses put forward for the causes of ovarian cancer. It is likely that subtle but common variants in these genes may impact on the individual's risk of disease.

We plan to compare particular genetic variants in the DNA from about 1,500 ovarian cancer cases to that from about 1,800 control women who do not have ovarian cancer. We will focus on genes that are involved in hormone synthesis and action and on those that repair damage to DNA, which can occur in a cell for a variety of reasons. If these repair genes are not working efficiently, it is likely that damaged DNA will be maintained instead of repaired. If the damage has occurred in genes involved in growth and spread of cells, cancer may result. Similarly, variants in genes that result in an excess of androgen in a woman may increase her risk of ovarian cancer. We are particularly interested in finding out if different genes cause different types of ovarian cancer and if certain women carrying particular genetic variants may be more susceptible to particular lifestyle factors.

The long-term aim of this project is to identify women at increased risk for ovarian cancer on the basis of their genetic makeup, because this will allow them to be targeted for early screening and detection and for intervention studies. Furthermore, understanding the genes that are important in ovarian cancer susceptibility is likely to increase our understanding of what biochemical pathways are altered in ovarian cancer. A better understanding of the biology is likely to lead to more directed therapies in the future.

JONES, REBECCA 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 multi-modal scanning configuration.
- c. Design of final optics.

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

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

Statement of Work

Follow-up Care for Men 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 pre-screened 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 Forms (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
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 representative earlier publications pertinent to this application. PAGE LIMITATIONS APPLY. DO NOT EXCEED THREE PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.			

Biographical Sketches

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

Biographical Sketches

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

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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3. Major Equipment	F-3
4. Materials, Supplies, and Consumables	F-3
5. Travel Costs	F-3
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10. Indirect Costs	F-4
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Detailed Cost Estimate Form.....	F-6

1. Personnel

- **Name:** Starting with the applicant, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the applicant of the proposal.
- **Role on Project:** Identify the role of each individual listed on the project. Describe his or her specific functions in the Justification section 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 of the Detailed Cost Estimate Form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.
- **Percentage of Effort on Project:** The qualifications of the applicant and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. 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 non-profit 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, strain (if applicable), and the number to be used.

5. Travel Costs

Travel costs are allotted as a flat rate that varies depending on award mechanism. Please consult the appropriate award mechanism section of this program announcement and enter the amount specified for travel in the Detailed Cost Estimate Form.

6. Research-Related Subject Costs

Itemize costs of subject 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. Research-Related Injury Medical Costs

Indicate costs for medical care for research-related injuries, should an injury to the subject occur as a result of the subject's participation in the proposed research. If the institution or state provides for this medical care as part of their existing liability insurance, annotate a cost of \$0.00 and indicate in the Justification section of the Detailed Cost Estimate Form that medical care for research-related injuries will be covered by existing institution/state insurance. If additional funds are needed to either supplement an existing policy or purchase a separate insurance policy to meet this requirement, annotate the budget requested and indicate in the Justification section of the Detailed Cost Estimate Form how medical care for research-related injuries will be covered, and whether the cost is charged as direct or indirect costs. The institution business office can assist applicants with budgeting for this requirement. Subject 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.

8. 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.

9. 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, fixed price);
- b. the identification of the proposed subcontractor or subgrantee, if known, 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.

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

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

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

11. 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 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 the second page should agree with the amount entered in the Proposal Information (see [Appendix C](#)).

12. Justification (third page of the Detailed Cost Estimate Form)

Each item in the budget should be clearly justified under the Justification section of the Detailed Cost Estimate Form.

13. Relocation of Applicant

Awards are made to institutions. If the applicant leaves the recipient institution, both the applicant and an official of the recipient institution should notify the U.S. Army Medical Research Acquisition Activity before the applicant leaves to discuss options for continued support of the research project.

Detailed Cost Estimate Form

Name of Applicant (*last, first, middle*)

DETAILED BUDGET					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
	Applicant						
SUBTOTALS ® ® ® ® ®							\$
CONSULTANT COSTS							
MAJOR EQUIPMENT (ITEMIZE)							
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)							
TRAVEL COSTS							
RESEARCH-RELATED SUBJECT COSTS							
RESEARCH-RELATED INJURY MEDICAL 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 Applicant (*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 SUBJECT COSTS						
RESEARCH-RELATED INJURY MEDICAL 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 IN THE PROPOSAL INFORMATION					\$	

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

Appendix F

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

Appendix G

General Information

Appendix G 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. An applicant should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support.

2. 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.

3. 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).

4. Government Obligation

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

5. 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.

6. 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
820 Chandler Street
Fort Detrick, MD 21702-5014

7. 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.

8. Equipment/Property

It is the policy of the Department of Defense that all commercial and non-profit recipients possess the equipment and facilities needed to support proposed research. In those rare cases when additional specific equipment is approved for commercial and non-profit 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 non-profit institutions of higher education or with non-profit organizations whose primary purpose is the conduct of scientific research. Normally, title will vest with the recipient organization if vesting will facilitate scientific research performed by the institution or organization for the Government.

Appendix H

Acronym List

ALT	Applicant's Local Time
CDMRP	Congressionally Directed Medical Research Programs
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
DOD	Department of Defense
DOEd	Department of Education
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities and Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
ITG	Institutional Training Grant
IRB	Institutional Review Board
M	Million
N/A	Not Applicable
OCRCP	Ovarian Cancer Research Program
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SEER	Surveillance Epidemiology and End Results Report
SOW	Statement of Work
TBN	To Be Named
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code