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FOREWORD

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed by the Secretary of the Army to continue the Department of Defense (DOD) Ovarian Cancer Research Program (OCRCP). The deadline, format, and other criteria specified for proposals in this OCRCP Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC website (<http://mrmc-www.army.mil>). Specific information on the DOD OCRCP can be obtained from the USAMRMC Congressionally Directed Medical Research Programs (CDMRP) website (<http://cdmrp.army.mil>). A copy of this Announcement and associated forms (except for the Proposal Cover Booklet; see Section 3 below) can also be downloaded from the USAMRMC CDMRP website (<http://cdmrp.army.mil>).

1. Inquiries

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

Fax: (301) 619-7792
Phone: (301) 619-7079
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRCP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

Every effort will be made to answer questions within 10 working days of receipt. Inquiries should be restricted to format issues only; no questions relating to technical proposal content or reasonableness/allowability of costs will be answered. Applicants should submit any written questions regarding this program as early as possible.

2. Forms

Associated forms (except for the Proposal Cover Booklet; see Section 3 below) can be found in the Appendices of the OCRCP Fiscal Year 1999 Program Announcement. The July 21, 1999 Program Announcement can be downloaded from the USAMRMC CDMRP website (<http://cdmrp.army.mil>).

3. Proposal Cover Booklet (Bubble Sheet)

A Proposal Cover Booklet must be completed for each submission according to the instructions found in Appendix B.

Proposal Cover Booklets must be requested via fax, phone, e-mail, or mail at the following addresses/numbers. Please allow sufficient time for delivery by regular mail.

Fax: (301) 682-5521
Phone: (301) 682-5501
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP99-Program Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

4. Proposal Submission

To be considered for award, submit the following documentation to the address at the end of this subsection:

Proposal: **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated photocopies (stapled or binder-clipped) of the **entire package**. **Every copy must match the original**. Do not use rubber bands, or spiral or three-ring binders.

Proposal Cover Booklet: **ONE** original (binder clipped to the original proposal) and **THREE** photocopies (*not* binder-clipped to proposal copies).

Abstract Pages: An additional **FIVE** copies of both the technical and the public (non-technical) abstracts in a manila envelope along with a 3½" computer disk containing the abstract pages [clearly labeled with the name of the principal investigator (PI), institution, and word processing program]. It is recommended that abstracts be formatted in Word, WordPerfect, or ASCII. **Note:** The abstracts are *vital* to the review of the proposal. Abstracts of all funded proposals will be reproduced in an OCRP abstract book and posted on the CDMRP website (<http://cdmrp.army.mil>).

Packaging: Package only **ONE** complete proposal submission (original plus all copies 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:

Administrative reasons for rejection of all or part of proposals most frequently result from failure to adhere to timelines, page limits, and font requirements. Noncompliance may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection.

Send the Proposal to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP99-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702

5. Deadline

The deadline for receipt of *all submissions* is **October 20, 1999 at 4:00 p.m. Eastern Time.**

Any proposal received by the USAMRMC after the exact time specified for receipt shall *not* be considered unless it is received before award is made, 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 (Post Office to Addressee: *Do not use Second Day Delivery*) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal 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, in its sole discretion, decides to accept the late proposal if it determines that no competitive advantage has been conferred, and the integrity of the competitive grants process will not be compromised.

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

6. Timeline

Proposal Receipt:	October 20, 1999
Peer Review:	December 1999
Request for Appendices:	Approximately 2 weeks after the completion of peer review
Programmatic Review:	February 2000
Notification:	February 2000
Award Date:	No earlier than April 1, 2000 and no later than September 30, 2000

Driving Directions to Fort Detrick

Directions from Washington, DC

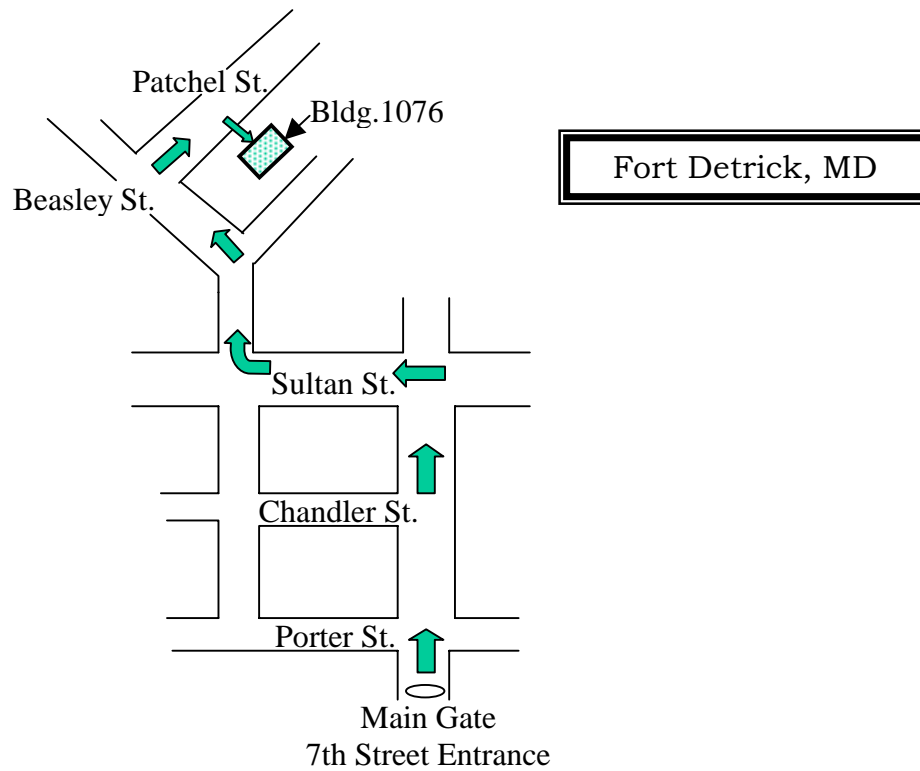
Take Interstate 495 to Interstate 270 North (exit #38) toward Rockville, Maryland. At Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to 7th Street exit. Turn right on 7th Street and go four blocks to Fort Detrick's Main Gate.

Directions from Baltimore, MD

Take Interstate 695 to Interstate 70 West. In Frederick, take exit 53, Route 15 North. Follow Route 15 North to 7th Street exit. Turn right on 7th Street and go four blocks to Fort Detrick's Main Gate.

Map of Fort Detrick

Packages to be delivered to the Ovarian Cancer Research Program should be delivered to building 1076 as shown on the map below. To gain entry to Ft. Detrick, you will be required to show your driver's license at the Main Gate. **Please allow at least 15 minutes to pass through gate area.**



Reference Table of Award Mechanisms and Submission Requirements

Award Mechanisms	Experience of PI	Key Category Elements	Dollars Available	Proposal Submission Deadline	Instructions for Proposal Preparation
Idea Awards	An independent investigator with any level of experience	<ul style="list-style-type: none"> • Reward innovative ideas and technology • No preliminary data required 	An average of \$100,000 per year in direct costs, for a maximum of \$200,000 over 2 years or \$300,000 over 3 years, plus indirect costs as appropriate	October 20, 1999 4:00 p.m. ET	Section III
New Investigator Awards	An independent investigator: (a) Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer, <i>or</i> (b) a more senior investigator new to the field of ovarian cancer research	<ul style="list-style-type: none"> • To support research on an issue relevant to ovarian cancer • Preliminary data required 	An average of \$100,000 per year in direct costs, for a maximum of \$300,000 over 3 years, plus indirect costs as appropriate	October 20, 1999 4:00 p.m. ET	Section IV

I. Overview of the Congressionally Directed Medical Research Programs

I-A. History of the Congressionally Directed Medical Research Programs

In the past decade, the work of consumer advocacy organizations has dramatically influenced the way scientific research is funded in this country. Beginning in fiscal year 1992 (FY92), the U.S. Congress has directed the Department of Defense (DOD) to manage various extramural and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the Office of the Congressionally Directed Medical Research Programs (CDMRP) to administer these funds. To date, \$1.1 billion has been targeted by Congress for research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense women's health, and osteoporosis. Together, these six programs are managed by the CDMRP.

For each appropriation, the CDMRP has developed and refined a flexible 6-year execution and management cycle that spans the development of an investment strategy through the conduct of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP programs. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to their program, to establish an appropriate investment strategy, and to perform programmatic review as described in Section I-B.2. Based upon this investment strategy, each program then employs a variety of award mechanisms to address the most urgent needs of a research community.

Overall, the CDMRP exists to support research that will impact upon the health of all Americans. The CDMRP strives to identify gaps in funding and provide award opportunities that will enhance program research objectives without duplicating existing funding opportunities. In meeting their goals, the CDMRP has developed unique mechanisms to facilitate funding of quality research that addresses individual program objectives.

I-B. Proposal Evaluation

The CDMRP uses a two-tiered review system for proposal evaluation, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals.

I-B.1. Scientific Peer Review

Scientific peer review is conducted by panels organized by scientific discipline or specialty area. The primary responsibility of the scientific peer review panels is to provide unbiased, expert advice on the scientific and technical merit of applications, based upon the review criteria developed for each award mechanism.

Each scientific review panel is composed of a chair, scientific reviewers, consumer reviewers, and a non-voting executive secretary. The chair and scientific reviewers are recognized leaders in their fields and are chosen on the basis of their scientific expertise. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their experience in scientific peer review. For the purposes of the Ovarian Cancer Research Program (OCRP), consumers are defined as ovarian cancer survivors. Consumer reviewers augment scientific merit review by bringing the patient and family perspectives to the assessment of science and relevance of the research.

Panel members rate each proposal based on the specific evaluation criteria developed for each award category (see Sections III-B and IV-B). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (low merit) to 10 (high merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global score using a scale of 1 (high merit) to 5 (low merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global score. A proposal may be disapproved at scientific peer review if it is so seriously flawed as to make its completion implausible, or if gravely hazardous or unethical procedures are involved.

The proposal summary statement is a product of scientific peer review. Each statement includes the investigator's technical and public (non-technical) abstracts (verbatim), the peer review global score, and an evaluation of the project as assessed by the peer reviewers according to evaluation criteria published in this Announcement. Summary statements not only assist investigators in assessing their research projects, but are forwarded to the next stage of the review process, programmatic review.

I-B.2. Programmatic Review

The second tier of the two-tiered review system is a programmatic review. Programmatic review is accomplished by an IP composed of scientists and consumer advocates. The scientific members of the IP represent many diverse disciplines and specialty areas, and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. With their firsthand experience, the consumer advocates enhance the review process by focusing attention upon critical patient issues and outcomes. The function of the IP is to conduct programmatic review to obtain a broad portfolio of grants across all disciplines and recommend an investment strategy for appropriated funds.

Programmatic review is a comparison-based process in which proposals from multiple research

Overview of the Congressionally Directed Medical Research Programs

areas compete in a common pool. IP members use the peer review summary statements to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded for programmatic review.

Programmatic review balances the potential outcomes and risks of scientifically excellent proposals. It should be emphasized that the IP is committed to funding a broad-based research portfolio. While the ratings and recommendations of peer review panels are important factors in programmatic review, the IP must also consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- ratings and recommendations of the peer review panels;
- programmatic relevance;
- scientific innovation; and
- program portfolio balance with respect to research disciplines or specialty areas.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are most likely to be recommended to the Commanding General, USAMRMC, for funding.

II. Department of Defense Ovarian Cancer Research Program

II-A. History of the Ovarian Cancer Research Program

A grassroots advocacy movement has heightened the political awareness of ovarian cancer as a major health issue. In FY97, Federal budgetary opportunities spurred Congress to appropriate \$7.5M to the DOD budget for an OCRP. Using the model established through recommendations from the Institute of Medicine for the USAMRMC Breast Cancer Research Program, the OCRP implemented a two-tiered scientific review process that funds meritorious research that fulfills Program goals. The Program's success has encouraged Congress to appropriate additional funds to the OCRP in subsequent years, culminating in a \$10M appropriation for the FY99 OCRP. Table II-1 provides an overview of the funding levels and awards made for the FY97-98 OCRP.

Table II-1: Program History

Fiscal Year	1997	1998	1999
OCRP Congressional Appropriations	\$7.5M	\$10M	\$10M
Funds for Research Awards	\$6.13M	\$8.6M	~\$5M-7.8M **
Number of Proposals Received	8	20	TBD***
Number of Research Awards	3	5*	TBD***

* Final numbers for FY98 will be available after September 30, 1999.

** Subject to additional reprogramming of dollars. To date, \$6M has arrived at the CDMRP.

*** To be determined.

II-B. FY99 Program Emphasis Areas

Recent advances in the understanding of ovarian cancer present unique opportunities that can benefit significantly from directed research efforts. Complementing current research initiatives by other funding agencies, the FY99 OCRP is offering to expand scientific inquiry in four research areas: (1) etiology, (2) prevention, (3) diagnosis, and (4) quality of life.

- ***Etiology***

Etiological research seeks to better understand the causes or origins of ovarian cancer. The lack of knowledge of the biology of ovarian cancer and the process of carcinogenesis is among the greatest barriers to progress in ovarian cancer research. Increased basic research in ovarian cancer etiology is an essential prerequisite for the development of new treatments and preventive mechanisms of ovarian cancer.

Department of Defense Ovarian Cancer Research Program

- ***Prevention***
Prevention research identifies both risk factors and effective prevention strategies for ovarian cancer. Studies to identify which factors contribute to ovarian cancer progression as well as studies to identify which interventions can prevent this progression are vital components of winning the war against ovarian cancer.
- ***Diagnosis***
National Cancer Institute Surveillance, Epidemiology and End Results Program data indicate that early detection/diagnosis of ovarian cancer is associated with improved survival. However, for most women, the cancer is not detected in its early stages. The CDMRP recognizes the crucial need for improved diagnostics, to include screening tools such as specific biochemical markers, targeted antibodies, and advanced imaging systems and techniques.
- ***Quality of Life***
While the mission of the OCRP is the eradication of ovarian cancer, many women are struggling to live with the diagnosis and treatment of the disease until this mission is fulfilled. The OCRP is interested in receiving proposals that focus on improving the quality of life of ovarian cancer patients. Some examples of quality of life research topics of interest are pain management, benefits of counseling, access to care, care following treatment, and genetic counseling.

Proposals that address the above research areas are sought across all areas of laboratory, clinical, behavioral, and epidemiological research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics.

Support for research done by scientists in the field, support for training of ovarian cancer researchers, and attraction of scientific experts from other fields are essential in the fight against ovarian cancer. Proposals are encouraged from investigators working at Historically Black Colleges and Universities and Minority Institutions (HBCU/MIs). Proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged from any institutions.

Prospective responders familiar with USAMRMC programs from previous years are urged to review this Program Announcement carefully, as revisions to award category definitions have been made.

II-C. Research Awards

From \$5M to \$7.8M will be allocated for Idea Awards (Section III) and New Investigator Awards (Section IV). The intent of both Idea Awards and New Investigator Awards is to stimulate and reward creative research ideas that may be viewed as speculative but have the potential for high payoff. The CDMRP is particularly interested in preparing new scientists for careers in ovarian cancer research and presenting an opportunity to move established investigators into the ovarian cancer field.

III. Idea Awards

III-A. Idea Awards

The intent of Idea Awards is to encourage innovative approaches to ovarian cancer research. The research focus of Idea proposals should address an issue relevant to ovarian cancer etiology, prevention, diagnosis, and/or quality of life. Proposals can be submitted by independent investigators of any experience level. Idea proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of ovarian cancer. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Idea Award proposals are qualitatively different from traditional research proposals as outlined in Table III-1 below. The inclusion of preliminary data is not required for Idea Award proposals; however, investigators must demonstrate a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning.

Table III-1: Differences between Traditional Research Proposals and Idea Research Proposals

Type of Proposal	Preliminary or Pilot Data	Description of Award Mechanism
Traditional Research	Required	Expansion of well-established avenues of research
Idea Award	Not required (can be included if available)	Novel, challenging existing paradigms; high risk

Funding for Idea Awards can be requested for an average of \$100,000 per year in direct costs. Idea Awards will require a 2 to 3 year research commitment. Funds can be requested for salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. A level of institutional support and commitment should be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. No more than one trip to a scientific meeting per award per year is funded. Please provide complete justification for expenses in each category.

Applicants may not submit the same proposal to more than one award category.

III-B. Scientific Peer Review – Evaluation for Idea Award

Idea Award proposals will be evaluated according to the following criteria:

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Preliminary data are not required but may be included. If included, do the preliminary data support the scientific rationale for the study?
- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms, develop new methodologies or technologies, or address underexplored or unexplored areas?
- **Scientific Relevance and Impact:** What will be the effect of these studies on the concepts or methods that drive this field? To what extent will the project, if successful, make an original and important contribution to the goal of conquering ovarian cancer and/or advancing research in the field? Does the proposal make a convincing case for the relevance of the research to ovarian cancer? Does this study address a critical problem in ovarian cancer research?
- **Principal Investigator:** Is the Principal Investigator (PI) independent, appropriately trained, and well suited to carry out this work? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?
- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?
- **Budget:** Is the budget reasonable for the research proposed?

III-C. Programmatic Review – Evaluation Criteria for Idea Award Proposals

Funding recommendations at the second tier of review, programmatic review, are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.2.

III-D. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” form as soon as possible. This form can be found in Appendix A and faxed, or it can be completed and submitted on-line via the CDMRP website:

Fax: (301) 682-5521
Website: <http://cdmrp.army.mil>

III-E. Proposal Preparation

The following proposal preparation information is specific for the Idea Award category. Specific instructions for proposal preparation are found in Appendix C of this Program Announcement. Please note that the body of the proposal is limited to 10 pages, inclusive of figures, tables and graphs, and that the deadline for receipt is **October 20, 1999 at 4:00 p.m. Eastern Time**. Proposed start dates should be no earlier than April 1, 2000 and no later than September 30, 2000.

1. Who May Apply – See Appendix C, part 1.
2. Proposal Acceptance Criteria – See Appendix C, part 2.
3. Proposal Cover Booklet – See Appendix C, part 3.
4. Peer Review Referral Page – See Appendix C, part 4.
5. Proposal Title Page – See Appendix C, part 5.
6. Table of Contents – See Appendix C, part 6.
Use the table of contents shown below in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

**Idea Award
Table of Contents**

	Page Number
Proposal Cover Booklet (12 pages)	
Peer Review Referral Page (no page limit)	i
Proposal Title Page (1 page limit).....	1
Table of Contents (1 page limit)	2
Technical Abstract (1 page limit).....	3
Public Abstract (1 page limit)	4
Statement of Work (2 page limit).....	5
Proposal Relevance and Impact Statement (1 page limit).....	7
Proposal Body (10 page limit).....	___
References (no page limit)	___
Biographical Sketches (3 page limit per PI and participating investigators)	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit)	___
Support Documentation (no page limit).....	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and Patent Abstracts (5 document limit)	___

7. Proposal Abstracts – See Appendix C, part 7.

8. Statement of Work – See Appendix C, part 8.

9. Proposal Relevance and Impact Statement – See Appendix C, part 9.

In addition, as part of the Proposal Relevance and Impact Statement, Idea Award applicants should explicitly state how the proposal will have an impact upon and further the programmatic goals.

10. Proposal Body – See Appendix C, part 10.

The body of Idea Award proposals (sections a – d below) is limited to 10 pages, inclusive of figures, tables, and graphs. Submission of color figures, tables, graphs, or photographs is not recommended.

For Idea Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Presentation of preliminary or pilot data is not required for Idea Awards, but can be included if available. In addition, the applicant should describe the proposed project using the **general** outline provided below:

- a. Background: Provide a brief statement of the ideas and reasoning behind the

Idea Awards

proposed work. Describe previous experience most pertinent to the proposal. Cite relevant literature references.

- b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.
- c. Objectives: State concisely the specific aims of the study.
- d. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the synthesis. All figures, tables, and diagrams must be included within the proposal body.

Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

- 11. References – See Appendix C, part 11.
- 12. Biographical Sketches – See Appendix C, part 12.
- 13. Existing/Pending Support – See Appendix C, part 13.
- 14. Facilities/Equipment Description – See Appendix C, part 14.
- 15. Support Documentation – See Appendix C, part 15.
- 16. Detailed Cost Estimate – See Appendix C, part 16.
- 17. Instruments – See Appendix C, part 17.
- 18. Publications and Patent Abstracts – See Appendix C, part 18.
- 19. Proposal Submission – See Appendix C, part 19.
- 20. Submission Deadline – See Appendix C, part 20.
The deadline for receipt of Idea Award proposals is **October 20, 1999 at 4:00 p.m. Eastern Time.**
- 21. Appendices – See Appendix C, part 21.
- 22. Notification – See Appendix C, part 22.

III-F. Reports

Timely submission of progress reports is a requirement of the USAMRMC. The PIs of Idea Awards should plan on a requirement that consists of:

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

The USAMRMC will notify PIs when these reports are due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in the scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

IV. New Investigator Awards

IV-A. New Investigator Awards

The intent of New Investigator Awards is to prepare new, independent investigators (Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer) for careers in ovarian cancer and to attract more senior investigators new to the ovarian cancer field. Preliminary or pilot data are required. The PI is required to submit several items of support documentation: a completed Statement of Eligibility form, and a letter of institutional support and commitment (see Section IV-E, item 15). The research focus of New Investigator Award proposals should address an issue relevant to ovarian cancer.

From \$5M to \$7.8M will be available for New Investigator Awards and Idea Awards. Funding for New Investigator Awards can be requested for an average of \$100,000 per year in direct costs for a maximum of \$300,000 over 3 years plus indirect costs as appropriate. Funds can be requested for salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded.

Applicants may not submit the same proposal to more than one award category.

IV-B. Scientific Peer Review Evaluation for New Investigator Awards

New Investigator Award proposals will be evaluated according to the following criteria:

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Do the required preliminary data support the scientific rationale for the study?
- **Scientific Relevance and Impact:** What will be the effect of these studies on the concepts or methods that drive this field? To what extent will the project, if successful, make an original and important contribution to the goal of conquering ovarian cancer and/or advancing research in the field? Does the proposal make a convincing case for the relevance of the research to ovarian cancer? Does this study address a critical problem in ovarian cancer research?
- **Principal Investigator:** Is the PI appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the ovarian cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?

New Investigator Awards

- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

IV-C. Programmatic Review – Evaluation Criteria for New Investigator Award Proposals

Funding recommendations at the second tier of review, programmatic review, are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.2.

IV-D. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” form as soon as possible. This form can be found in Appendix A and faxed, or it can be completed and submitted on-line via the CDMRP website:

Fax: (301) 682-5521
Website: <http://cdmrp.army.mil>

IV-E. Proposal Preparation

The following proposal preparation information is specific for the New Investigator Award category. Specific instructions for proposal preparation are found in Appendix C of this Program Announcement. Please keep in mind that a requirement of the New Investigator Award category is that the PI be an independent investigator (Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer) *or* a more senior investigator new to the field of ovarian cancer. The Statement of Eligibility form found at the end of this subsection must be completed and submitted with the proposal. In addition, please note that the body of the proposal is limited to 10 pages and that the deadline for submission is **October 20, 1999 at 4:00 p.m. Eastern Time**. Proposal start dates should be no earlier than April 1, 2000 and no later than September 30, 2000.

1. Who May Apply – See Appendix C, part 1.
2. Proposal Acceptance Criteria – See Appendix C, part 2.
3. Proposal Cover Booklet – See Appendix C, part 3.
4. Peer Review Referral Page – See Appendix C, part 4.

New Investigator Awards

5. Proposal Title Page – See Appendix C, part 5.
6. Table of Contents – See Appendix C, part 6.
Use the table of contents shown below in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

**New Investigator Awards
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	Page Number
Proposal Cover Booklet (12 pages)	
Peer Review Referral Page (no page limit)	i
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Statement of Work (2 page limit).....	5
Proposal Relevance and Impact Statement (1 page limit).....	7
Proposal Body (10 page limit).....	___
References (no page limit)	___
Biographical Sketches (3 page limit per PI and participating investigators)	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit)	___
Support Documentation (no page limit)	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and Patent Abstracts (5 document limit)	___

7. Proposal Abstracts – See Appendix C, part 7.
8. Statement of Work – See Appendix C, part 8.
9. Proposal Relevance and Impact Statement – See Appendix C, part 9.
In addition to the instructions found in Appendix C, part 9, New Investigator Award applicants should state explicitly how the proposed work is innovative and relevant to ovarian cancer research. Articulate how the combination of innovation and relevance in the proposal will impact and further the programmatic goals. Describe how the project will make a contribution to the goal of conquering ovarian cancer and/or advancing research in the field.
10. Proposal Body – See Appendix C, part 10.
The body of New Investigator Award proposals (sections a – d below) is limited to 10

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pages inclusive of figures, tables, and graphs. Submission of color figures, tables, graphs, or photographs is not recommended. Presentation of preliminary or pilot data is required. In addition, the PI should describe the proposed project using the **general** outline provided below:

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- b. **Hypothesis/Rationale/Purpose:** State the hypothesis to be tested and the expected results.
- c. **Objectives:** State concisely the specific aims of the study.
- d. **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the synthesis. All figures, tables, and diagrams must be included within the proposal body.

Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix C, part 11.

12. Biographical Sketches – See Appendix C, part 12.

13. Existing/Pending Support – See Appendix C, part 13.

14. Facilities/Equipment Description – See Appendix C, part 14.

15. Support Documentation – See Appendix C, part 15.

In addition to the instructions found in Appendix C, part 15, applicants for a New Investigator Award must submit a form signed by the Department Chair, Dean, or equivalent official indicating that the PI is an independent investigator (Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer) *or* a more senior investigator new to the field and, therefore, an eligible applicant for this award type. The Statement of Eligibility form at the end of this subsection should be used.

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A letter of institutional support must also be included in this section. The letter shall include a discussion of the level of institutional commitment to foster the applicant's research career as reflected by (1) the extent to which the applicant will be relieved of his or her academic responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) the opportunities for critical professional interaction with senior colleagues.

16. Detailed Cost Estimate – See Appendix C, part 16.

17. Instruments – See Appendix C, part 17.

18. Publications and Patent Abstracts – See Appendix C, part 18.

19. Proposal Submission – See Appendix C, part 19.

20. Submission Deadline – See Appendix C, part 20.

The deadline for receipt of New Investigator Award proposals is **October 20, 1999 at 4:00 p.m. Eastern Time.**

21. Appendices – See Appendix C, part 21.

22. Notification – See Appendix C, part 22.

STATEMENT OF ELIGIBILITY

Name of Applicant: _____

Title of Proposal: _____

Name of Applicant's Organization: _____

Location of Applicant's Organization: _____

Signature of Applicant: _____

STATEMENT OF ELIGIBILITY

For the purposes of the Department of Defense Congressionally Directed Medical Research Programs' Ovarian Cancer Research Program New Investigator Award category as outlined in the Announcement, the applicant fulfills all of the following criteria:

holds a position of Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer;

OR

is a more senior investigator who is new to the field of ovarian cancer research;

AND

has his/her own independent research facilities;

I, _____ of _____

(printed name of Department Chair, Dean or equivalent official) (printed name of institution)
attest that the above-named investigator fulfills the requirements for a New Investigator Award.

Signature of Official _____ Date: _____

IV-F. Reports

Timely submission of progress reports is a requirement of the USAMRMC. The PIs of New Investigator Awards should plan on a requirement that consists of:

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

The USAMRMC will notify PIs when these reports are due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in the scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their contract specialist for guidance.