

DEPARTMENT OF DEFENSE

**OVARIAN CANCER
RESEARCH PROGRAM**

FISCAL YEAR 2000

PROGRAM ANNOUNCEMENT

APRIL 28, 2000

Headquarters, U.S. Army Medical Research and Materiel Command
MCMR-PLF, 1077 Patchel Street
Fort Detrick, Maryland 21702-5024

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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 (OCRP). The deadline, format, and other criteria specified for proposals in this OCRP fiscal year 2000 (FY00) Program Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC web site at <http://mrmc-www.army.mil>. Specific information on the DOD OCRP can be obtained from the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil>. A copy of this Program Announcement and associated forms (except for the Proposal Cover Booklet; see section 4 on the following page) also can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce> and <http://cdmrp.army.mil/?/announce/forms>, respectively.

1. Inquiries

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

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRPO0-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

Applicants should submit questions via e-mail or in writing regarding this program as early as possible. Every effort will be made to answer questions within 5 working days of receipt.

2. Research Involving Human Subjects and/or Anatomical Substances

All proposals submitted with research involving human subjects and/or anatomical substances must be approved by the appropriate local review board. Proposals must also be approved by the U.S. Army Human Subjects Research Review Board (HSRRB). The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board (see Appendix H). Therefore, all investigators submitting such proposals must comply with the requirements detailed in Appendix H **before funds can be awarded.**

3. Forms

Associated forms (except for the Proposal Cover Booklet; see section 4 below) can be found in the Appendices of this Program Announcement and can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>.

4. Proposal Cover Booklet (Bubble Sheet)

A Proposal Cover Booklet must be completed for each proposal according to the instructions found in Appendix C. (Please note that for a Program Project submission, a completed Proposal Cover Booklet is required for each Research Project and Core Facility as well as the Overall Program.)

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

Phone: 301-682-5501
Fax: 301-682-5521
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP00-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

5. Proposal Submission

To be considered for Ovarian Cancer New Investigator and Program Project Awards, submit the following documentation to the address at the end of this section:

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

Statement(s) of Work: **TWO** additional copies of each Statement of Work in the same manila clasp envelope with abstract copies and disk.

Packaging: Package **ONE** complete proposal submission (original plus all materials requested above) per box. If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the proposal title and PI's name.

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

Send the Proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP00-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

6. Receipt Deadlines

The receipt deadline for Ovarian Cancer New Investigator and Program Project Award proposals solicited in this Program Announcement is September 13, 2000 at 4:00 p.m. Eastern Time.

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

1. It was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. It was sent by U.S. Postal Service Express Mail Next Day Delivery to the address listed in section 5 (Proposal Submission) above (**do not use Second Day Delivery**) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline, or
3. It was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline for delivery by 4:00 p.m. Eastern Time on the due date, or

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

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

7. Duplicate Submissions

The same research project can be submitted to only **one** of the two award mechanisms published in this Program Announcement.

8. Previously Submitted Proposals

Resubmissions of previously reviewed proposals are acceptable. However, the applicant should be cautioned that the year-to-year status of funding for the OCRP does not permit the establishment of standing panels for scientific peer review (see Section I-C). Therefore, the submission of a revised proposal does not guarantee any funding advantage or an improved global priority score. Resubmitted/amended proposals should meet the requirements for the appropriate award category in this Program Announcement and adhere to this year's format guidelines. Do not include summary statements of previously reviewed proposals.

9. Timeline

The timeline for Ovarian Cancer New Investigator and Program Project Awards is:

Letter of Intent:	As soon as possible but no later than August 30, 2000
Proposal Receipt Deadline:	September 13, 2000 at 4:00 p.m. Eastern Time
Peer Review:	November 2000
Request for RCQ ¹ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	January 2001
Notification:	Approximately 2 weeks after the completion of programmatic review
Award Date:	No earlier than June 1, 2001 and no later than September 30, 2001

¹ Regulatory Compliance and Quality

Driving Directions to Fort Detrick

From Washington, DC

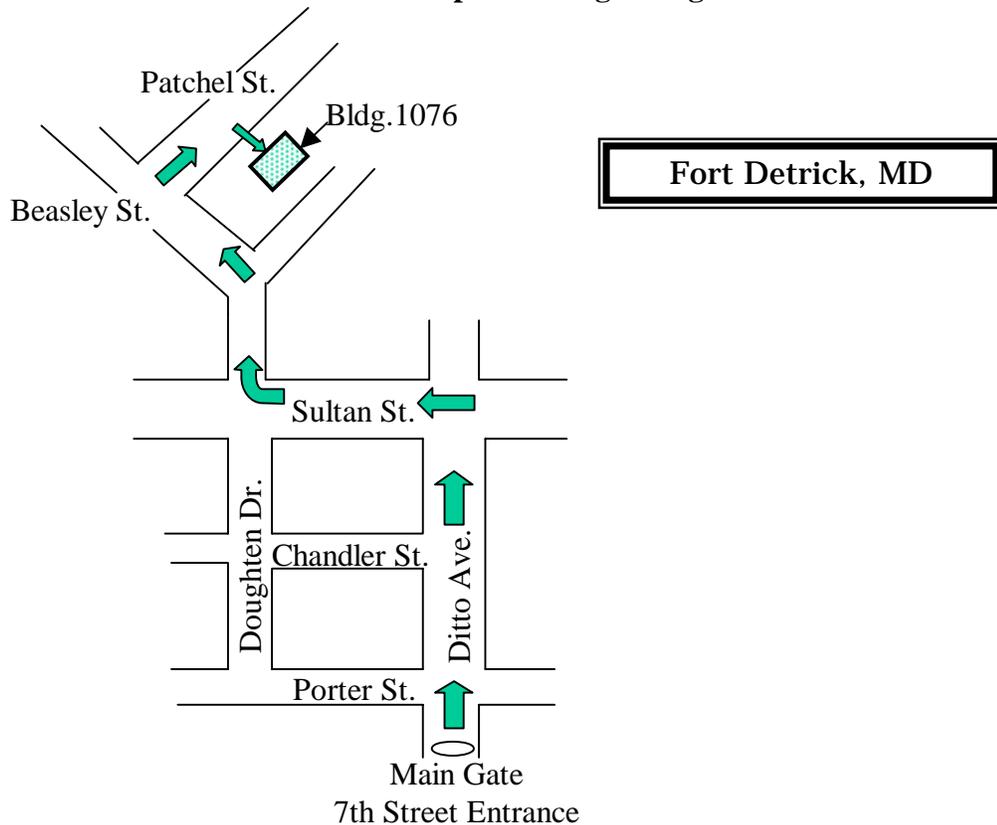
Take Interstate 495 to Interstate 270 North (exit 38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

From Baltimore, MD

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

Map of Fort Detrick

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



Reference Table of Award Mechanisms and Submission Requirements

Award Mechanisms	Experience of PI	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
Ovarian Cancer New Investigator Awards	An independent investigator must be (a) an 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 in one or more program emphasis areas (etiology, early detection/ diagnosis, preclinical therapeutics, and/or quality of life) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma • Preliminary or pilot 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	September 13, 2000 4:00 p.m. Eastern Time	Section III
Program Project Awards	The Program Project Director must be an investigator with a record of leadership and scientific ability	<ul style="list-style-type: none"> • To establish new multidisciplinary programs in ovarian cancer research • <i>Synergistic</i> program incorporating two to four research projects and one to two core facilities • To support research in one or more program emphasis areas (etiology, early detection/ diagnosis, preclinical therapeutics, and/or quality of life) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma • Preference will be given to those that do not have active DOD OCRP Program Project grants as solicited in the FY97 and FY98 Program Announcements, National Cancer Institute (NCI) Program Project grants in ovarian cancer, or NCI Specialized Program of Research Excellence (SPORE) grants for ovarian cancer research (see Section IV-A) 	A maximum award limit of \$2M, inclusive of direct and indirect costs, over a 2- to 4-year performance period	September 13, 2000 4:00 p.m. Eastern Time	Section IV

I. Overview of the Congressionally Directed Medical Research Programs

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

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage various extra- and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, \$1.5 billion has been targeted by Congress for research on breast, prostate, and ovarian cancer; neurofibromatosis; Defense women's health; osteoporosis; and other specified areas.

The CDMRP exists to support research that will positively impact 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. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that address individual program objectives.

I-B. Investment Strategy

For each program, the CDMRP has developed and refined a flexible 7-year execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to the program, establish an appropriate investment strategy, and perform programmatic review as described in Section I-C.2. Based upon this investment strategy, each program then uses a variety of award mechanisms to address the most urgent needs of the research community.

I-C. Proposal Evaluation

The CDMRP uses a two-tiered review process for proposal evaluation, which consists of scientific peer 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 scientific 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-C.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 proposals, based upon the review criteria developed for each award mechanism.

Each scientific peer review panel is composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. The chair and scientific reviewers are recognized leaders in their fields. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. For the breast, prostate, and ovarian cancer research programs, consumer reviewers are cancer survivors and representatives of consumer advocacy organizations; for the neurofibromatosis research program, consumer reviewers are individuals with neurofibromatosis or their family members and representatives of consumer advocacy organizations. Consumer reviewers are nominated by an advocacy organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the scientific peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (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 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed as to make its completion implausible.

The peer review summary statement is a product of scientific peer review. Each statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this Program Announcement. Summary statements assist investigators in assessing research projects and are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier of the two-tiered review process is programmatic review. Programmatic review is accomplished by the IP, composed of scientists, clinicians, 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 firsthand experience, consumer

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

The IP is committed to funding a broad-based research portfolio. The ratings and recommendations of scientific peer review panels are primary factors in programmatic review; the IP also must consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and recommendations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation;
- Program portfolio balance with respect to research disciplines or specialty areas; and
- Other equitable factors, e.g., geographic distribution and adequate support for new investigators.

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

I-D. Notification

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

I-E. Annual and Final Reports

All awards will require the timely delivery of several reports during the research effort. These reports are necessary for the CDMRP to monitor progress.

The principal investigator (PI) should plan on a reporting requirement consisting 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.

In accordance with the Bayh-Dole Act (35 USC¹ 200 et seq.), title to inventions and patents resulting from federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain a royalty-free, nonexclusive license to such inventions. Funded investigators must contact their Contract Specialist and follow the instructions in the award document concerning license agreements and patents.

¹ United States Code

II. Department of Defense Ovarian Cancer Research Program

II-A. History of the Ovarian Cancer Research Program

Grassroots advocacy organizations have heightened the political awareness of ovarian cancer as a major health issue. In fiscal year 1997 (FY97), federal budgetary opportunities spurred Congress to appropriate \$7.5 million (M) to the Department of Defense (DOD) budget for an Ovarian Cancer Research Program (OCRP). Using the model established through recommendations from the Institute of Medicine for the U.S. Army Medical Research and Materiel Command (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 \$12M appropriation for the FY00 OCRP. A summary program history for FY97-99 appropriations of the OCRP is shown in Table II-1 below.

Table II-1: History of the DOD's Peer-Reviewed OCRP

Program History	FY97	FY98	FY99
OCRP-Managed Appropriations for Peer-Reviewed Research	\$7.5M	\$10M	\$10M
Number of Full Proposals Received	8	20	194
Program Project Award Submissions ¹	8	20	N/A ²
Idea Award and New Investigator Award Submissions	N/A	N/A	194
Number of Proposals Funded	3	5	~18 ³
Program Project Awards ¹	3	5	N/A
Idea Awards and New Investigator Awards	N/A	N/A	~18

¹ Includes awards granted to Comprehensive Cancer Centers in FY97.

² Not applicable as this type of award was not offered during this program cycle.

³ Final numbers for FY99 will be available after September 30, 2000.

II-B. Overview of the FY00 OCRP

The USAMRMC, through this Program Announcement, is soliciting applications for ovarian cancer research. The objective of the OCRP is to fund a balanced portfolio of scientifically meritorious research in ovarian cancer. The key initiatives of the OCRP are encouraging established scientists in the ovarian cancer field, attracting new scientific expertise from other fields, and building infrastructure. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic 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. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

The USAMRMC is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring scientific expertise into the field of ovarian cancer research. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the CDMRP wishes to encourage risk-taking research, such projects nonetheless must demonstrate solid scientific judgment and rationale.

II-C. FY00 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 FY00 OCRP is encouraging scientific inquiry of epithelial ovarian carcinoma, the most common form of ovarian cancer, and/or primary peritoneal carcinoma, a disease with a similar clinical history as epithelial ovarian carcinoma. In addition, emphasis on one or more of the following research areas is encouraged: (1) etiology, (2) early detection/diagnosis, (3) preclinical therapeutics, 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.
- ***Early Detection/Diagnosis***
National Cancer Institute Surveillance, Epidemiology and End Results (SEER) 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, including screening tools such as specific biochemical markers, targeted antibodies, and advanced imaging systems and techniques.
- ***Preclinical Therapeutics***
In an effort to encourage the development of new and effective ovarian cancer therapies, the CDMRP is interested in receiving proposals that focus on preclinical therapeutics. Topics of interest are, for example, drug resistance and development of new chemotherapeutic agents.

- ***Quality of Life***

Many women are struggling to live with the diagnosis and treatment of ovarian cancer. For this reason, 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, access to care, care following treatment, and genetic counseling.

II-D. OCRP Award Opportunities

The OCRP adapts the types of award mechanisms it offers each year to meet the current needs in ovarian cancer research and treatment. The programmatic strategy for FY00 is to fund proposals in two award mechanisms: (1) Ovarian Cancer New Investigator Awards (Section III) and (2) Program Project Awards (Section IV). Ovarian Cancer New Investigator Awards are targeted to investigators in the early phase of their careers and to investigators established in other fields who desire to move into ovarian cancer research. The intent of Program Project Awards is to enhance the ovarian cancer research infrastructure by establishing collaborations in ovarian cancer research across research disciplines and institutions as well as attracting and supporting ovarian cancer investigators. For the FY00 OCRP, an estimated \$9.9M¹ will be available to fund competitive peer-reviewed research.

Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this Program Announcement carefully, as revisions to award mechanism definitions and requirements have been made.

¹ A total of \$12M was appropriated by Congress to fund the OCRP in FY00. Prior to receipt of these funds by the CDMRP, the DOD withholds approximately 7.9% for Congressionally mandated and DOD initiatives. Of the remainder, an additional 10% is set aside to manage the program, including costs for peer and programmatic review of proposals and administration of the grants throughout their entire performance period (up to 7 years).

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III. Ovarian Cancer New Investigator Awards

III-A. Ovarian Cancer New Investigator Awards Overview

The intent of Ovarian Cancer 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 research) for careers in ovarian cancer and to attract more senior investigators new to the ovarian cancer research field. Ovarian Cancer New Investigator Award proposals should address one or more program emphasis areas (i.e., etiology, early detection/diagnosis, preclinical therapeutics, and/or quality of life; see Section II-C) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Preliminary or pilot data are required. In addition, submissions by Historically Black Colleges and Universities/Minority Institutions are encouraged.

Funding for Ovarian Cancer 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 and expenses, including research supplies, equipment, and travel to scientific meetings.

Please note that only one Ovarian Cancer New Investigator Award proposal may be submitted per applicant. In addition, a proposal submitted to the Ovarian Cancer New Investigator Award mechanism may not be submitted as part of a Program Project Award proposal.

For complete proposal preparation requirements, please refer to Section III-E and Appendix B. Additional guidance for proposal preparation may be gained by reviewing the scientific peer and programmatic review criteria listed in Sections III-B and III-C.

III-B. Scientific Peer Review Evaluation Criteria for Ovarian Cancer New Investigator Award Proposals

Ovarian Cancer 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 or pilot data support the scientific rationale for the study? If statistical analyses are appropriate, is there a clear statistical plan, including power analysis, outlined in the proposal?
- **Scientific Relevance:** To what extent will the project, if successful, make an original and important contribution to research in the field? Does the proposal make a convincing case for the relevance of the research to epithelial ovarian carcinoma and/or primary peritoneal carcinoma?

- **Principal Investigator (PI):** 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 collaborators (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?
- **Environment:** Is the scientific environment appropriate 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?

III-C. Programmatic Review Evaluation Criteria for Ovarian Cancer New Investigator Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, How will the proposal contribute to research in the field? Will the project lead to new insights into ovarian cancer etiology, early detection/diagnosis, preclinical therapeutics, and/or quality of life? Does the proposal meet the intent of the Ovarian Cancer New Investigator Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

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” by August 30, 2000**, 2 weeks prior to the proposal receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil/?/announce/forms>.

III-E. Proposal Preparation

Instructions for proposal preparation are found in Appendix B of this Program Announcement. The following proposal preparation information is specific for Ovarian Cancer New Investigator Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of figures, tables, and graphs, and that the proposal **receipt deadline is September 13, 2000 at 4:00 p.m. Eastern Time**.

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
4. Peer Review Referral Page – See Appendix B, part 4.
5. Proposal Title Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.
Use the table of contents found on page III-5 in your proposal submission. Number all pages at the bottom center, beginning with the Proposal Title Page. It is recommended that this table of contents be used as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Structured Technical Abstract and Lay Abstract – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.
In addition to the instructions found in Appendix B, part 10, Ovarian Cancer New Investigator Award applicants should state explicitly (within the 1-page limit) how the proposed work is relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Describe how the project will contribute to research in the field.
11. Proposal Body – See Appendix B, part 11.
The body of Ovarian Cancer New Investigator Award proposals is limited to **10 pages**. Figures, tables, and graphs, if used, must be included in this section. If color figures are submitted, it is recommended that they be provided in all copies. Presentation of preliminary or pilot data is required.

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.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

The Statement of Eligibility form found on page III-7 must be signed by a Department Chair, Dean, or equivalent official to verify that the applicant is (1) a new, 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** (2) that the applicant has his/her own independent research facilities and therefore is an eligible applicant for this award type.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Ovarian Cancer New Investigator Award proposals is September 13, 2000 at 4:00 p.m. Eastern Time.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

Do not submit this information with your proposal. It will be requested at a later time if required.

Principal Investigator: _____

Proposal Title: _____

**Ovarian Cancer New Investigator Awards
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Statement of Work (2-page limit)	6
Proposal Relevance Statement (1-page limit)	___
Proposal Body (10-page limit).....	___
Abbreviations (1-page limit)	___
References (no page limit)	___
Biographical Sketches (3-page limit each)	
PI.....	___
Key Personnel (including collaborating investigators and support staff).....	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
Statement of Eligibility Form.....	___
Letters of Support and/or Collaboration (as applicable)	___
Detailed Cost Estimate (no page limit).....	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (5-document limit)	___

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STATEMENT OF ELIGIBILITY

Name of Applicant: _____

Title of Proposal: _____

Name of Applicant's Organization: _____

Location of Applicant's Organization: _____

Signature of Applicant: _____

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

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

or

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

AND

(2) has his/her own independent research facilities;

I, _____, _____
(printed name of Department Chair, Dean, or equivalent official) Title

of _____
(printed name of institution)

attest that the above-named investigator fulfills the requirements for an Ovarian Cancer New Investigator Award.

Signature of Official: _____ Date: _____

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IV. Program Project Awards

IV-A. Program Project Awards Overview

The intent of Program Project Awards is to enhance ovarian cancer research infrastructure by engaging experts from multiple disciplines to establish ovarian cancer research programs that will advance investigations in the field. Two important goals of these awards are to establish multidisciplinary programs that will foster an environment conducive to groundbreaking research in ovarian cancer and to ensure the continuance of excellent ovarian cancer research beyond the completion of the funding period.

Program Projects must be innovative, multidisciplinary, synergistic, and integrated around one or more program emphasis areas (i.e., etiology, early detection/diagnosis, preclinical therapeutics, and/or quality of life) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma (see Section II-C). These awards are designed to stimulate research that addresses new paradigms in the study of ovarian cancer, challenges existing paradigms, or looks at an existing problem from a new perspective.

Please note that clinical trial proposals will not be considered for funding due to the limited availability of funds. In addition, a proposal submitted to the Ovarian Cancer New Investigator Award mechanism may not be submitted as part of a Program Project proposal.

Program Project Awards should foster multidisciplinary collaborations in ovarian cancer research among established and promising investigators. Program Project Award proposals must contain at least two but no more than four integrated **Research Projects**. In addition, at least one but no more than two **Core Facilities** must support the proposed work. Funding for Core Facilities can be for new Cores specifically focusing on ovarian cancer or for the enhancement of existing Cores that will incorporate ovarian cancer facilities for the first time.

Collaborations between institutions, particularly Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) and non-HBCU/MI, are encouraged. Collaborations established through Program Projects should result in a *synergistic* program rather than an additive set of subprojects; that is, the combined efforts in the whole program should provide greater benefit than the sum of individual research initiatives. The Program Project Director, i.e., the principal investigator (PI) of the overall proposal, should have a proven track record of leadership and scientific ability. In addition, the Program Project Director should have the training and expertise to oversee the multidisciplinary research of the Program Project.

Proposals should contain distinct descriptions of the overall proposed work as well as each individual Research Project and Core Facility. In addition, a strong institutional commitment of resources and space is required for successful competition of Program Project Awards. No mechanism is available to provide additional support after the current project period. Therefore,

the proposal must address how the institutional commitment will be established and how support for the program will be sustained beyond the grant's performance period if the proposal is selected for funding.

Funding for Program Project awards can be requested for a maximum of \$2 million (M), inclusive of direct and indirect costs, over a 2- to 4-year performance period.

Eligible Institutions

The fiscal year 2000 (FY00) Program Projects funding effort is envisioned as a catalyst for a broader national ovarian cancer research enterprise. Consistent with this vision and to extend infrastructure to a greater number of institutions, preference will be given to those institutions that **do not** have active ovarian cancer Program Project-type grants at the release date of this Program Announcement. Specifically, institutions that do not have active Department of Defense (DOD) Ovarian Cancer Research Program (OCRCP) Program Project grants as solicited in the FY97 and FY98 Program Announcements, National Cancer Institute (NCI) Program Project grants in ovarian cancer, or NCI Specialized Program of Research Excellence (SPORE) grants for ovarian cancer research, will be given preference for funding. **Collaborations** between a new applicant institution **and** investigators from institutions with an active ovarian cancer DOD Program Project, NCI Program Project, or NCI SPORE are allowed.

IV-B. Scientific Peer Review Evaluation Criteria for Program Project Proposals

Scientific peer review of Program Project proposals will involve two phases. First, each Research Project and Core Facility within a Program Project will be evaluated separately according to the criteria listed in the following sections (see Sections IV-B.2 and IV-B.3). Then, the Overall Program section of the proposal will be evaluated according to the criteria in Section IV-B.1. To be eligible for funding, each Program Project application must include (1) a minimum of two but no more than four Research Projects, and (2) a minimum of one but no more than two Core Facilities.

IV-B.1 Scientific Peer Review Evaluation Criteria for the Overall Program

The Overall Program section of the proposal will be evaluated according to the following criteria:

- **Scientific Relevance:** Is the proposed Program Project relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma? Is the proposed research likely to generate a new understanding of ovarian cancer research?
- **Proposed Research and Research Management Plan:** Are scientifically excellent Research Projects and Core Facility(ies) proposed? Is the proposed research multidisciplinary? Are the proposed Research Projects and Core Facility(ies) well integrated and synergistic, i.e., are the combined efforts of the Program Project of greater benefit than the sum of individual research initiatives? Has a management plan been outlined to coordinate and optimize the resources,

collaborations, and Core services available within the Program Project and available to it from other sources?

- **Program Project Director (the PI of the overall proposal):** Is there evidence that the Program Project Director has the leadership, experience, and scientific ability to successfully coordinate and lead the proposed Program Project? Does the Program Project Director have the training and expertise to oversee the multidisciplinary research of the Program Project and ensure an emphasis on epithelial ovarian carcinoma and/or primary peritoneal carcinoma?
- **Research Environment/Institutional Commitment:** Is there evidence of a strong institutional commitment to sustain the long-term goals of the effort? Have adequate resources been allocated to support the overall research goals of the Program Project? Is the institutional research environment supportive of the effort?
- **Budget:** Is the budget reasonable for the proposed research? Is each Research Project and Core Facility adequately funded to perform the research/services presented? Are adequate funds requested to ensure success of the entire Program Project?

IV-B.2 Scientific Peer Review Evaluation Criteria for Research Projects

Each Research Project within the Program Project 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? Are they based on sound scientific rationale and logical reasoning? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Has a sound scientific rationale been presented through a critical review and analysis of the literature and/or logical reasoning? If statistical analyses are appropriate, is there a clear statistical plan, including power analysis, outlined in the proposal?
- **Scientific Relevance:** Does this study address epithelial ovarian carcinoma and/or primary peritoneal carcinoma? To what extent will the project, if successful, make an original and important contribution to research in the field? Does the proposal make a convincing case for the relevance of the research to ovarian cancer?
- **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?

- **Principal Investigator and Staff:** Does the PI show potential for contributing 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? If statistical analyses are appropriate, are personnel with the necessary statistical expertise included?
- **Environment:** Is the scientific environment appropriate 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-B.3 Scientific Peer Review Evaluation Criteria for Core Facilities

Each proposed Core Facility will be evaluated according to the following criteria:

- **Integration and Function:** Is the proposed Core Facility well integrated with each Research Project and the overall goals of the Program Project? Will the Core Facility provide high quality services required by the Research Projects? Is the facility adequate to provide these services?
- **Personnel:** Are the Core Facility PI and key staff well qualified to perform the Core services and functions? How will the personnel ensure integration and delivery of Core services and functions to each Research Project?
- **Budget:** Is the budget reasonable for the proposed Core services and functions?

IV-C. Programmatic Review Evaluation Criteria for Program Project Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, How will this proposal advance the field of ovarian cancer research? How well does the proposal meet the intent of the Program Project Award mechanism?

Please be reminded that the intent of the Program Project Award mechanism is to enhance ovarian cancer research infrastructure by engaging experts from multiple disciplines to establish ovarian cancer research programs that will advance investigations in the field. These awards should result in a *synergistic* program rather than an additive set of subprojects, that is, combined efforts in the whole program should provide greater benefit than the sum of individual research initiatives. Therefore, the Congressionally Directed Medical Research Programs (CDMRP) Integration Panel will give funding priority to synergistic Program Projects of high scientific quality and programmatic relevance. Please note that programmatic reviewers may elect to recommend funding an individual Research Project but not the entire Program Project.

Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

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” by August 30, 2000**, 2 weeks prior to the proposal receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>.

IV-E. Proposal Preparation

A Program Project submission must consist of the following sections:

- An Overall Program,
- A minimum of two and a maximum of four Research Projects, and
- A minimum of one and a maximum of two Core Facility(ies).

Refer to Sections IV-E.1, IV-E.2, and IV-E.3 for each proposal section’s specific proposal preparation requirements. Please note that the proposal **receipt deadline is September 13, 2000 at 4:00 p.m. Eastern Time.**

IV-E.1. Proposal Preparation – Overall Program Section

General instructions for proposal preparation are found in Appendix B of this Program Announcement. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

The following proposal preparation information is specific for the Overall Program section of the proposal.

1. Who May Apply – See Appendix B, part 1.
Preference will be given to those institutions that **do not** have active DOD OCRP Program Project grants as solicited in the FY97 and FY98 Program Announcements, NCI Program Project grants in ovarian cancer, or SPORE grants for ovarian cancer research.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
A Proposal Cover Booklet must be completed for the Overall Program proposal section.

4. Peer Review Referral Page – See Appendix B, part 4.
A Peer Review Referral page must be completed for the Overall Program.
5. Proposal Title Page – See Appendix B, part 5.
A Proposal Title Page must be completed for the Overall Program.
6. Table of Contents – See Appendix B, part 6.
Use the Table of Contents found on page IV-9 in your proposal submission. Number all pages at the bottom center, beginning with the Proposal Title Page. It is recommended that PIs use this table of contents as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
A Checklist for Proposal Submission must be completed for the Overall Program.
8. Structured Technical Abstract and Lay Abstract – See Appendix B, part 8.
For the Overall Program, provide structured technical and lay abstracts that describe the overall aspects of the Program Project. It is important to emphasize the innovative, thematic, multidisciplinary, and synergistic aspects of the Overall Program. Please note that each Research Project and Core Facility will require its own structured technical and lay abstracts.
9. Statement of Work – **Not required** for the Overall Program.
10. Proposal Relevance Statement – See Appendix B, part 10.
A Proposal Relevance Statement must be completed for the Overall Program. The Overall Program proposal section should state explicitly how the proposed work is innovative and relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Describe how the combination of innovation and relevance in the proposal will contribute to research in the field.
11. Proposal Body – See Appendix B, part 11.
The Overall Program proposal body is limited to **10 pages**. Figures, tables, and graphs, if used, must be included within this section. If color figures are submitted, it is recommended that they be provided in all copies.

For the **Overall Program** proposal body, describe the proposed Program 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. **Purpose:** State the purpose of the Program Project and the expected results or outcomes.

- c. Themes/Objectives: State concisely the goals of the Overall Program. Describe the theme relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Address the multidisciplinary and synergistic aspects of the program and describe how the program will have a major impact on ovarian cancer research. Include information regarding the institutional support for the effort and plans to continue the program beyond the grant's performance period if the proposal is selected for funding.
 - d. Management Plan: Describe the management plan to coordinate and optimize the resources, collaborations, and Core services available within the Program Project and available to it from other sources. Emphasize how the proposed management plan will integrate individual Research Projects and Core Facility(ies) into a cohesive overall effort, linking individual Research Project/Core Facility goals to the overall research strategy.
12. Abbreviations – See Appendix B, part 12.
 13. References – See Appendix B, part 13.
 14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

On the first page of the Biographical Sketch section for the Overall Program, present a *list* of all the participants, starting with the Program Project Director followed by the participants for each Research Project, and each Core Facility as shown in the example on page IV-11. The biographical sketch of the Program Project Director and other key personnel involved in the Overall Program should be included in this section. Biographical sketches of other Program Project participants should not be included in the Overall Program proposal section but should be included within the individual Research Project and/or Core Facility proposal sections as appropriate.
 15. Existing/Pending Support – See Appendix B, part 15.

In the Overall Program description, only Existing/Pending Support for investigators who are not included within individual Research Projects or Core Facility proposal sections should be provided. Do not duplicate Existing/Pending Support information described in the Research Project and Core Facility proposal sections.
 16. Facilities/Equipment Description – See Appendix B, part 16.

In the Overall Program description, include any Facilities/Equipment Description not included within individual Research Projects or Core Facility(ies). Describe how existing shared or Core services will be accessed and utilized.

17. Administrative Documentation – See Appendix B, part 17.

In the Overall Program proposal section, provide a letter from a Dean, President, or appropriate official confirming institutional support for the establishment of a Program Project, matching funds for any proposed construction, and plans to continue the program beyond the funding provided by this application as described in the Themes/Objectives section of the proposal body.

18. Overall Program Cost Estimate – See page IV-13.

For the Overall Program Cost Estimate, please use the form on page IV-13. Bring forward the amounts from each Research Project and each Core Facility from the Detailed Cost Estimate Form found in Appendix F onto the Overall Program Cost Estimate Form. It is essential that the Program Project Director ensure that the total costs from the individual Research Projects and Core Facility(ies) are correctly summated in the Overall Program Cost Estimate.

The maximum amount of funds allowed for the entire Program Project is \$2M, inclusive of direct and indirect costs, over a 2- to 4-year performance period. In the Budget Justification section, provide itemized documentation of any consortium or collaborative costs that are not otherwise described in the individual Research Project sections or the Core Facility section(s). The amount allotted for travel is \$1,800 per year per PI (Program Project Director and each Research Project and Core Facility PI) to attend scientific/technical meetings.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

Do not submit this information with your proposal. It will be requested at a later time if required.

Program Project Director: _____

Proposal Title: _____

**Program Project Award Proposal: Overall Program
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Proposal Body (10-page limit)	7
Abbreviations (1-page limit)	___
References (no page limit)	___
List of Participants for the Entire Proposal	___
Biographical Sketches (3-page limit each)	
Program Project Director and other key personnel.....	___
Existing/Pending Support (no page limit)	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
Letter confirming institutional support for the establishment of the Program Project	___
Overall Program Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and Patent Abstracts (5-document limit)	___

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EXAMPLE

List of Participants for the Entire Proposal

[List all essential personnel and their position in the application.]

Program Project Director: Joe Green, M.D., Ph.D.

Performance sites: Outstanding University, Nirvana, IN; Respectable Institute, Respectable, IN

Research Project 1: Model 12345 for Intraperitoneal Spread of Ovarian Cancer

Project PI: Joe Green, M.D., Ph.D.

Co-investigator: Barbara Black, R.N., Ph.D.

Research Project 2: Determinants of Decision-Making for Patients with Ovarian Carcinoma

Project PI: Susan Blue, R.N., Ph.D.

Co-investigator: Steven Teal, M.P.H., M.S.W.

Consultant: Joe Grey, Ph.D.

Research Project 3: A New Imaging Method for Epithelial Ovarian Carcinoma and Primary Peritoneal Carcinoma

Project PI: Carol Indigo, Ph.D.

Co-investigator: Thomas Red, M.D.

Co-investigator: Chris Violet, M.P.H.

Core Facility A: Biostatistics

Core Facility PI: Joe Green, M.D., Ph.D.

Co-investigator: Barbara Black, R.N., Ph.D.

Co-investigator: Charles Yellow, Ph.D.

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Overall Program Cost Estimate Form (Budget for Entire Proposed Period of Support)

Principal Investigator (last, first, middle):

Budget Category Totals*	Overall Program (costs not included in Project or Core budgets)	Projects and Cores						Total
		Project 1 (Required)	Project 2 (Required)	Project 3 (Optional)	Project 4 (Optional)	Core A (Required)	Core B (Optional)	
Personnel								
Fringe Benefits								
Consultant Costs								
Major Equipment								
Materials, Supplies, and Consumables								
Travel Costs								
Research-Related Patient Costs								
Other Expenses								
Subtotal Direct Costs (not including Consortium Costs)								
Direct Consortium Costs								
Indirect Consortium 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**								

Program Project Awards

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* Provide itemized documentation of any consortium or collaborative costs that are not otherwise described in the individual Research Project sections or the Core Facility section(s) on the *Justification* page that follows.

** This amount should agree with that entered on the Proposal Cover Booklet, item #4.

Program Project Awards

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

IV-E.2. Proposal Preparation – Research Project Sections

General instructions for proposal preparation are found in Appendix B of this Program Announcement. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

The following proposal preparation information is specific for Research Projects within a Program Project proposal.

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
A Proposal Cover Booklet must be completed for each Research Project.
4. Peer Review Referral Page – See Appendix B, part 4.
A Peer Review Referral page must be completed for each Research Project.
5. Proposal Title Page – See Appendix B, part 5.
A Proposal Title Page must be completed for each Research Project. Start the title with “Research Project” and assign it the appropriate number (e.g., Research Project 1: Model 12345 for Intraperitoneal Spread of Ovarian Cancer; Research Project 2: Determinants of Decision-Making for Patients with Ovarian Carcinoma).
6. Table of Contents – See Appendix B, part 6.
Use the table of contents on page IV-19 in your proposal submission. Number all pages at the bottom center, beginning with the Proposal Title Page. It is recommended that PIs use this table of contents as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
A Checklist for Proposal Submission must be completed for each Research Project.
8. Structured Technical Abstract and Lay Abstract – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.
In addition to the instructions found in Appendix B, part 10, Research Project applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Articulate how the combination of innovation and relevance in the proposal will have an impact upon and further programmatic goals.

11. Proposal Body – See Appendix B, part 11.

Each Research Project proposal body is limited to **10 pages**. Figures, tables, and graphs, if used, must be included within this section. If color figures are submitted, it is recommended that they be provided in all copies.

For each Research Project, 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/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. If statistical analyses are appropriate, provide a clear statistical plan, including power analysis.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

Biographical Sketches for Research Project investigators, collaborators, and other key personnel should be included within this section. Biographical sketches of participants in multiple individual Research Projects and/or the Core Facility(ies) should be duplicated in each relevant proposal section.

15. Existing/Pending Support – See Appendix B, part 15.

Existing/Pending Support for investigators involved in the Research Project should be included within this section.

16. Facilities/Equipment Description – See Appendix B, part 16.

Facilities/Equipment Description for Research Projects should be included within this section. Do not duplicate information provided in the Core Facility section(s).

17. Administrative Documentation – See Appendix B, part 17.

Program Project Awards

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Use the Detailed Cost Estimates in Appendix F to provide budgetary information to be brought forward to the Overall Program Detailed Cost Estimate Form. The maximum amount of funds allowed for the entire Program Project is \$2M inclusive of direct and indirect costs over a 2- to 4-year performance period. The amount allotted for travel is \$1,800 per year per PI (Program Project Director and each Research Project and Core Facility PI) to attend scientific/technical meetings.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

Do not submit with your proposal. This information will be requested at a later time if required.

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Program Project Director (PI): _____

Overall Program Title: _____

Research Project PI: _____

Project Number and Title: _____

**Program Project Award Proposal: Research Project
Table of Contents**

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Statement of Work (2-page limit)	6
Proposal Relevance Statement (1-page limit)	___
Proposal Body (10-page limit)	___
Abbreviations (1-page limit)	___
References (no page limit)	___
Biographical Sketches (3-page limit each)	
PI	___
Key Personnel (including collaborating investigators and support staff).....	___
Existing/Pending Support (no page limit)	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
Letters of Support and/or Collaboration (as applicable)	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and Patent Abstracts (5-document limit)	___

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IV-E.3. Proposal Preparation – Core Facility Section(s)

General instructions for proposal preparation are found in Appendix B of this Program Announcement. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

The following proposal preparation information is specific for a Core Facility within a Program Project proposal.

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
A Proposal Cover Booklet must be completed for each Core Facility.
4. Peer Review Referral Page – See Appendix B, part 4.
A Peer Review Referral page must be completed for each Core Facility.
5. Proposal Title Page – See Appendix B, part 5.
A Proposal Title Page must be completed for each Core Facility. Start the title with “Core Facility” and assign it the appropriate letter (e.g., Core Facility A: Biostatistics; Core Facility B: Tissue Bank).
6. Table of Contents – See Appendix B, part 6.
Use the table of contents on page IV-25 in your proposal submission. Number all pages at the bottom center, beginning with the Proposal Title Page. It is recommended that this table of contents be used as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
A Checklist for Proposal Submission must be completed for each Core Facility.
8. Structured Technical Abstract and Lay Abstract – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.
In addition to the instructions found in Appendix B, part 10, Core Facility applicants should state explicitly (within the 1-page limit) how the proposed work is relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Articulate how the Core Facility will have an impact upon and further programmatic goals. Describe how the Core will make a contribution to research in the field.

11. Proposal Body – See Appendix B, part 11.

Each Core Facility Proposal Body is limited to **10 pages**. Figures, tables, and graphs, if used, must be included within this section. If color figures are submitted, it is recommended that they be provided in all copies.

For each Core Facility, describe the proposed project using the **general** outline provided below:

- a. **Function:** Describe the resources or services that the Core Facility will provide to the Overall Program, the facilities to support these services, and the anticipated usage of these facilities.
- b. **Integration:** State concisely how the proposed Core Facility will integrate the Research Projects and the overall goals of the Program Project. Address how personnel will ensure integration and delivery of services and functions to each project.
- c. **Methods:** Give details about the experimental techniques and methodology of services provided. If the methodology is new or unusual, describe it in sufficient detail for evaluation. If statistical analyses are appropriate, provide a clear statistical plan, including power analysis.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

Biographical Sketches for Core Facility investigators, collaborators, and other key personnel should be included within this section. Biographical sketches of participants in multiple Core Facility(ies) and/or individual Research Projects should be duplicated in each relevant proposal section.

15. Existing/Pending Support – See Appendix B, part 15.

Existing/Pending Support for individuals involved with the Core Facility should be included within this section.

16. Facilities/Equipment Description – See Appendix B, part 16.

The Facilities/Equipment Description for the Core Facility should be included within this section. Include a description of how the proposed Core Facilities are to be accessed and utilized. This may duplicate some information provided in the Overall Program section of the proposal.

17. Administrative Documentation – See Appendix B, part 17.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Use the Detailed Cost Estimates in Appendix F to provide budgetary information to be brought forward to the Overall Program Cost Estimate Form. The maximum amount of funds allowed for the entire Program Project is \$2M, inclusive of direct and indirect costs, over a 2- to 4-year performance period. Please note, existing Core Facilities for which no funds are being requested should be described in Facilities/Equipment Description. If construction is proposed as part of a Core Facility effort, institutional matching funds of 50 percent are required. Construction is permitted only for renovations of facilities that are required to support the project. Requests for construction funds should be clearly justified. In addition, the amount allotted for travel is \$1,800 per year per PI (Program Project Director and each Research Project and Core Facility PI) to attend scientific/technical meetings.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

Do not submit this information with your proposal. It will be requested at a later time if required.

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Program Project Director (PI): _____

Overall Program Title: _____

Core Facility PI: _____

Core Facility Letter and Title: _____

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