DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
OVARIAN CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT

March 13, 2002

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 to continue the Department of Defense (DOD) Ovarian Cancer Research Program (OCRP). The deadline, format, and other criteria specified for proposals in this DOD Fiscal Year 2002 (FY02) OCRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity (USAMRAA), the Congressionally Directed Medical Research Programs (CDMRP), and the DOD OCRP can be obtained from the CDMRP web site at http://cdmrp.army.mil. A copy of this program announcement and associated forms also can be downloaded from the CDMRP web site (for information on completing the Proposal Information, see Section 6, page iii of this Foreword and Appendix C).

1. Highlights of Changes from the FY01 Program Announcement

- No paper copies of this Program Announcement will be supplied by the CDMRP. The document and its associated appendices can be downloaded from the CDMRP web site (http://cdmrp.army.mil).

- Two award mechanisms, Idea Development Awards and Institutional Training Grants, are being offered in FY02. Please review Sections III and IV carefully for specific details about these award mechanisms.

- This year's program is encouraging scientific inquiry of epithelial ovarian carcinoma and/or peritoneal carcinoma as related to the following research areas: etiology, prevention, early detection/ diagnosis, and preclinical therapeutics.

- Letters of Intent to submit proposals to the FY02 OCRP are requested and should be submitted electronically through http://cdmrp.army.mil/funding/02ocrp1

- The paper Proposal Cover Booklet has been replaced by Proposal Information found online at http://cdmrp.org/proposals. Please see Appendix C for more information.

- Margins for proposal preparation and acceptance have been changed to a minimum of 0.5-inch top, bottom, right, and 1-inch left with a print area not to exceed 7.0 x 10.0 inches (approximately 19 cm x 25.5 cm).

- An authorized Administrative Representative from the Sponsored Programs Office at the applicant's organization will be **required to submit one electronic version of the applicant's proposal as a PDF (Portable Document Format) file through the Internet (electronic submission)**; the

electronic PDF file will serve as the official proposal submission. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

- The Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance documents have been incorporated into Appendix B and are due with the proposal submission; additional documents related to Regulatory Compliance and Quality (RCQ) issues will be available on the CDMRP web site by April 2002. You will be notified if you need to submit these additional RCQ documents to support your submission.
- All submissions to the OCRP that involve human subjects must provide medical care for research-related injuries at no cost to the subject. Investigators should plan on budgeting for such costs.

2. Who May Apply

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. Please refer to Sections III and IV for additional eligibility criteria.

3. Submission Deadlines

The proposal submission deadline is **June 18, 2002**. An electronic PDF version of your proposal, which will serve as the official proposal submission, must be uploaded/submitted through the Internet by an authorized Administrative Representative of the Sponsored Programs Office (or equivalent) of your organization no later than **11:59 p.m. (applicant's local time) June 18, 2002**. See Appendix B, part 22, and Appendix C for additional details. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

4. Timeline

Electronic Letter of Intent:	As soon as possible but no later than June 4, 2002
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) June 18, 2002**.
Peer Review:	August 2002
Programmatic Review:	November 2002
Notification/Request for RCQ[1] Documents:	December 2002
Award Date:	Between January 2003 and September 2003

[1] Regulatory Compliance and Quality

5. Inquiries

Questions concerning the proposal format 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 (OCRP02)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

Applicants should submit questions regarding this program as early as possible. Every effort will be made to answer questions within 5 working days.

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

6. Proposal Submission

Applicants should refer to Sections III and IV and Appendix B for appropriate submission requirements.

Proposals will be submitted electronically at http://cdmrp.org/proposals. The web site will be available for proposal submission by May 7, 2002. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must upload/submit one electronic PDF version of the applicant's proposal, which will count as the official proposal submission.

Several steps are critical for successful electronic submission of the applicant's proposal:

1. The applicant is required to submit Proposal Information (referred to in previous years as the Proposal Cover Booklet) online at http://cdmrp.org/proposals, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf (see Appendix C). **The Proposal Information must be submitted prior to submission of the proposal. We encourage applicants to begin this part of the submission process at least 2 weeks prior to the proposal submission deadline.**

2. Once the applicant has submitted the Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.

3. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Applicants are encouraged to coordinate early with their Sponsored Programs Office.

4. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. The Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the web site (http://cdmrp.org/proposals) no later than **11:59 p.m. (applicant's local time) June 18, 2002.** Detailed instructions for electronic submissions will be available at http://cdmrp.org/proposals no later than May 7, 2002.

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 for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received more than $2.2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, 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 opportunities that will enhance program research objectives without duplicating existing funding. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that addresses individual program objectives.

I-B. Investment Strategy

For each program, the CDMRP has developed and refined a flexible 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 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 published for each award mechanism.

Scientific peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. 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 Section B of each award mechanism). 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 that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary 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 are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The 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. One of the functions of programmatic review is to select a broad portfolio of grants across all disciplines.

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 to programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and evaluations 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 evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative 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 selected by the IP and 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 award status of his or her proposal, along with the peer review summary statement. Letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

I-E. Negotiation of the Award

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving the U.S. Army Medical Research Acquisition Activity (USAMRAA) and Regulatory Compliance and Quality (RCQ). A Contract Specialist from USAMRAA will contact the administrative representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

Please note that the award start date will be determined during the negotiation process.

Concurrent with the USAMRAA discussions, RCQ will review the environmental compliance, safety plan, animal use, and human subjects/anatomical substance use documents to ensure that Army regulations are met. The Certificate of Environmental Compliance and Principal Investigator Safety

Program Assurance documents are part of the proposal submission. The Facility Safety Plan (if needed), Research Involving Animals, and Research Involving Human Subjects and/or Anatomical Substances documents will be requested in the applicant's notification letter and will be reviewed by RCQ staff. All documents related to RCQ should be available on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

I-F. Human Use Requirements Unique to Department of Defense-funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects, a second, DOD review and approval is also required. The Human Subjects Research Review Board (HSRRB), administered by the USAMRMC RCQ Office, is responsible for conducting this second level of review. 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. **All research protocols involving human subjects and/or anatomical substances must be approved by both the appropriate local review board and by the HSRRB before awards are made and prior to initiation of the research protocol.**

Two requirements specific to DOD-funded research that the applicant must specifically address, if applicable, in the development of a research proposal for submission to the DOD are outlined below.

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

- Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative. Therefore, the applicant should articulate how the research will benefit minors or other individuals that are not legally competent to consent and are part of the placebo arm of the study.

More information regarding research involving human subjects can be found in the RCQ Document, "Research Involving Human Subjects and/or Anatomical Substances," which will be available on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

I-G. 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 and evaluate program outcomes.

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 award period) that details the findings and issues for the entire project.

I-H. Publications and Patents

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. For example, "This research, under award number DAMD…, was supported by the Department of Defense Ovarian Cancer Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI must submit a copy of any manuscript or publication resulting from research funded under the award to the CDMRP.

In accordance with the Bayh-Dole Act (35 USC[1] 200 et seq.), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement 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's (USAMRMC's) Breast Cancer Research Program, the OCRP implemented a two-tiered review process, which 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 $10.2M appropriation for the FY02 OCRP.

A summary of the program history for FY97-01 OCRP appropriations is shown in Table II-1 below.

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

Program History	FY97-00	FY01
OCRP-Managed Appropriations for Peer-Reviewed Research	$39.5M	$12M
Number of Full Proposals Reviewed	340	23
Program Project Awards	39	23
New Investigator Awards	162	N/A[1]
Idea Awards	139	N/A
Number of Proposals Funded[2]	40	~5
Program Project Awards	11	~5
Investigator-Initiated Research Project	1	N/A
New Investigator Awards	16	N/A
Idea Awards	12	N/A

[1] Not applicable, since this type of award was not offered during this program cycle.
[2] Final numbers for FY01 will be available after September 30, 2002.

II-B. Overview of the Fiscal Year 2002 Ovarian Cancer Research Program

The Congressionally Directed Medical Research Programs (CDMRP) is requesting proposals on ovarian cancer research and training through this program announcement. Proposals will be requested in two award mechanisms: Idea Development Awards and Institutional Training Grants.

The overall goal of this announcement is to promote research directed toward eliminating ovarian cancer. Within this context, the key initiative of the FY02 OCRP is to support innovative, integrated, multidisciplinary research efforts that will lead to a better understanding, detection, diagnosis, prevention, and control of ovarian cancer.

The CDMRP is challenging the scientific community to design innovative ovarian cancer research that will foster new directions, address neglected issues, and train new investigators in ovarian cancer research. As in previous years, the central theme of the OCRP is innovation. Scientific ventures that address underinvestigated avenues of research, novel applications of existing technologies, or advanced new concepts are highly sought. Although the CDMRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

II-C. Fiscal Year 2002 Ovarian Cancer Research 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 FY02 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) prevention, (3) early detection/diagnosis, and (4) preclinical therapeutics.

Etiology

Etiological research seeks to better understand the causes or origins of ovarian cancer. The limited knowledge of ovarian cancer biology and the process of carcinogenesis are 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 preventive mechanisms and treatments of ovarian cancer.

Prevention

Recognizing the importance of disease prevention, the OCRP is encouraging innovative approaches to ovarian cancer prevention. Research may focus on the development of innovative instrumentation, methods, and preventive approaches, and their feasibility, implementation, and dissemination as related to 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 OCRP recognizes the crucial need for improved diagnostics, including screening tools such as specific biochemical markers, targeted antibodies, and novel imaging systems and techniques.

Preclinical Therapeutics
In an effort to encourage the development of new and effective ovarian cancer therapies, the OCRP is interested in receiving proposals that focus on preclinical therapeutics. Examples include, but are not limited to, understanding drug resistance and developing new chemotherapeutic agents.

II-D. Fiscal Year 2002 Ovarian Cancer Research Program Award Opportunities

For the FY02 OCRP, this Command anticipates that $8.5M will be available to fund competitive peer reviewed ovarian cancer research proposals. The programmatic strategy for the FY02 OCRP is to fund research proposals in two award mechanisms: (1) Idea Development Awards (Section III) and (2) Institutional Training Grants (Section IV). The intent of Idea Development Awards is to stimulate and reward creative research ideas that may be viewed as high risk but have the potential for high return in scientific and clinical knowledge. All investigators are eligible to submit proposals, however, preliminary data are required. The objective of Institutional Training Grants is to support postdoctoral training programs in ovarian cancer. These awards should draw postdoctoral trainees focused on ovarian cancer research together in a stimulating research and training environment.

Approximately $6.7M and $1.8M will be allocated for Idea Development Awards and Institutional Training Grants, respectively.

Prospective applicants who are familiar with the OCRP submission requirements from previous years are urged to review this program announcement carefully because revisions have been made.

Reference Table of Award Mechanisms

The table below summarizes key elements of the Idea Development Award and Institutional Training Grant award mechanisms. Refer to Sections III and IV for further details and proposal preparation instructions. Please note that the proposal submission deadline is **11:59 p.m. (applicant's local time) June 18, 2002**.

Award Mechanism	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available	Submission Deadline	Instructions for Proposal Preparation
Idea Development Awards	All levels of experience	• Rewards innovative ideas and technology • Preliminary data required	$375,000 for direct costs over a 3-year period of performance plus indirect costs	June 18, 2002 11:59 p.m. ALT[1]	Section III
Institutional Training Grants	All levels of experience	• To support postdoctoral training programs in ovarian cancer research	$600,000 inclusive of direct and indirect costs over a 3-year period of performance	June 18, 2002 11:59 p.m. ALT	Section IV

[1] Applicant's Local Time

III. Idea Development Awards

III-A. Idea Development Awards

The intent of Idea Development Awards is to encourage innovative approaches to ovarian cancer research. Idea Development Awards must address one or more of the program emphasis areas (i.e., etiology, prevention, early detection/diagnosis, and/or preclinical therapeutics) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma (see Section II-C). Investigators from all academic levels are eligible to submit proposals. All Idea Development Award proposals **must include preliminary data relevant to ovarian cancer research and the proposed project**. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment.

Innovation is the pivotal feature of the Idea Development Award. Idea Development Award proposals should represent the start of something new; they should create or introduce a unique or unusual approach to the study of ovarian cancer. Research that is innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives.

As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including the following:

- Study concept - investigation of a novel idea and/or unique research question
- Research method or technology - use of novel research methods or new technologies to address a research question
- Clinical interventions - use of a novel method or technology for preventing, diagnosing, or treating ovarian cancer
- Adaptations of existing methods or technologies – application or adaptation of existing methods or technologies for (1) research purposes that are fundamentally different from those originally intended and/or (2) use in novel research purposes.

This list is not all-inclusive, but is intended to serve as a foundation on which to frame and present the innovative features of the proposal.

Approximately $6.7M will be available for Idea Development Awards. Funding for Idea Development Awards can be requested for a maximum of $375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

III-B. Scientific Peer Review Evaluation Criteria for Idea Development Award Proposals

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

- **Innovation:** Is the proposed research innovative in one or more of the following areas: study concept or question; research methods or technologies; adaptations of existing methods or technologies; or in any other areas? Does the project propose new paradigms or challenge existing paradigms? Is innovation necessary for the project?

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental design, methods, and analyses adequately developed and well integrated to the aims of the project? Is there a clear-cut rationale supporting the research provided? Does the applicant acknowledge potential problem areas and consider methods/alternative tactics? Do the required ovarian cancer-relevant preliminary data support the proposed project?

- **Disease 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 the goal of eliminating 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?

- **Personnel:** Is the applicant appropriately trained to carry out this work? Does the applicant show potential for contribution to the ovarian cancer field? Is the proposed work appropriate to the experience level of the applicant and other researchers (if applicable)? Is appropriate expertise available to conduct the study successfully?

- **Environment:** Is the scientific environment appropriate for the proposed research? Do necessary resources and appropriate collaborative arrangements adequately support the research requirements? Is there evidence of institutional support provided with the proposal?

- **Budget**: Is the budget appropriate for the research proposed?

III-C. Programmatic Review Evaluation Criteria for Idea Development 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. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2. Proposals must be scientifically sound and fulfill the programmatic evaluation criteria. In addition, applicants must effectively address how the proposal will contribute to the program's goal of eliminating ovarian cancer and/or advancing research in the field.

III-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent by June 4, 2002. This form can be submitted via the CDMRP web site at http://cdmrp.army.mil/funding/02ocrp1

III-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Development Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** The applicant is required to submit Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) June 18, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1.
   Investigators from all academic levels are eligible to submit Idea Development Award proposals.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the applicant's name (last name, first name, middle initial) and the proposal log number. (A proposal log number will be automatically assigned to your proposal when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – 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, Idea Development 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 proposal will contribute to the goal of eliminating ovarian cancer and/or advancing research in the field.

11. Proposal Body – See Appendix B, part 11.
    The body of Idea Development Award proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used. The inclusion of promising and well-founded preliminary data relevant to ovarian cancer research and the proposed project is required for Idea Development proposals. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

    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. Include preliminary data relevant to ovarian cancer research. 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.

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.
    Provide the following items in the Administrative Documentation section.

    Provide letter(s) of support from the applicant's institution and collaborating investigators (if applicable) in the Administrative Documentation section of the proposal submission.

Note: The signed letter(s) of support from the institution and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Idea Development Awards can be requested for a maximum of $375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs, (if applicable; see Part 7 of Appendix F) and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

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

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. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative from your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 18, 2002. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The 1-page Certificate of Environmental Compliance and 1-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Proposal Log Number: _____

Applicant: _____
Last Name *First Name* *MI*

Proposal Title: _____

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IV. Institutional Training Grants

IV-A. Institutional Training Grants

Institutional Training Grants (ITGs) are intended to support postdoctoral training programs in ovarian cancer research. These awards should draw postdoctoral trainees focused on ovarian cancer research together in a common research and training environment. These grants should emphasize the training of postdoctoral trainees who have an underlying interest in ovarian cancer research. Eligible postdoctoral trainees should have been in the laboratory in which this research is to be performed no more than 2 years at the time of submission and may have up to 5 years of postdoctoral experience (exclusive of clinical residency or fellowship training). ITGs must address one or more program emphasis areas (i.e., etiology, prevention, early detection/diagnosis, and preclinical therapeutics) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Inclusion of postdoctoral trainees from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) is encouraged.

ITG proposals should address the following key aspects of the proposed postdoctoral training program: (1) the program vision and goals, (2) the program faculty, (3) the training program and trainees, and (4) the proposed research areas. As part of the discussion of each of these key aspects, the body of the proposal should address:

- the scientific emphasis of the program,
- the proposed research areas in which postdoctoral trainees will be trained,
- the structure of the training program to integrate ovarian cancer research,
- the training environment and history,
- the physical environment,
- the qualifications of the Program Director,
- the training faculty for postdoctoral programs,
- the selection criteria for postdoctoral trainees,
- the recruitment of postdoctoral trainees into the program, and
- the method of assigning trainees to a faculty mentor.

As part of the proposal, the following training support documentation shall be included in the appropriate proposal sections to provide greater detail on selected requirements discussed in the body of the submission:

1. faculty biographical sketches with a section describing previous training experiences and mentoring,
2. an expanded description of the training environment and facilities,
3. a list of current and pending grant support for the proposed faculty mentors, and
4. a letter of support from the institution.

A maximum of four postdoctoral trainees is recommended. Eligible postdoctoral trainees should have been in the laboratory in which this research is to be performed no more than 2 years at the time of submission and may have up to 5 years of postdoctoral experience (exclusive of clinical residency or fellowship training). To Be

Named (TBN) postdoctoral trainees are acceptable for the proposal. When TBN trainees are ultimately selected, the name and biographical sketch of each candidate must be provided for approval by the Congressionally Directed Medical Research Programs (CDMRP)

Approximately $1.8M will be available for ITGs. Funding for ITGs can be requested for a maximum of $600,000 inclusive of direct and indirect costs over a 3-year period of performance. These funds can cover postdoctoral salary, faculty salary, seminars and courses, administrative support (e.g., photocopying charges, telephone and fax services, secretarial support, etc.), travel to scientific meetings, and limited supplemental funds for research supplies excluding animal purchase. The amount allotted for travel is $1,500 per year per postdoctoral trainee. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests.

III-B. Scientific Peer Review Evaluation Criteria for Institutional Training Grant Proposals

ITG proposals will be evaluated according to the following criteria:

- **Training Program:** Does the postdoctoral training program offer a structured, well-rounded, focused experience in ovarian cancer research? Does the program support opportunities for collaboration and communication with various members of the training faculty, and involvement in other institutional research activities? Will the postdoctoral training in the proposed research areas prepare trainees for independent careers in ovarian cancer research?

- **Program Director and Training Faculty:** Does the Program Director have the background, research qualifications, and ability to lead and manage the training program successfully? Is there a diverse, well-qualified faculty available to provide multiple, suitable training opportunities for trainees in the program? What are the research interests and the past training records of the individual faculty members? Do the faculty members have sufficient research support available to conduct their own research programs? How will interaction and communication between the trainees and the faculty be optimized?

- **Trainees:** What methods are used to recruit postdoctoral trainees? Are the selection criteria for admitting trainees into the program appropriate to select highly qualified postdoctoral trainees? If applicable, what is the overall quality of present and former trainees? Have former trainees made significant contributions to cancer research and, more specifically, to ovarian cancer research?

- **Disease Relevance:** Does the institution make a convincing case for its commitment to develop a postdoctoral training program that will be relevant to ovarian cancer research? To what extent will the training program make an important contribution to advancing research in the field?

- **Institutional Environment:** Is there a strong institutional commitment to research training in ovarian cancer? Does the institution provide an intellectually stimulating environment and facilitate interaction among faculty and trainees? Does the institution provide adequate laboratory facilities, equipment, and other relevant resources to support the research and training activities?

- **Budget:** Is the budget appropriate for the work proposed?

IV-C. Programmatic Review Evaluation Criteria for Institutional Training Grants

Funding recommendations at this second tier of 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-C.2. Proposals must be scientifically sound and fulfill the programmatic evaluation criteria. In addition, applicants must effectively address how the proposal will contribute to the program's goal of eliminating ovarian cancer and lead to new insights into the etiology, prevention, diagnosis/detection, and/or preclinical therapy of ovarian cancer.

IV-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent by June 4, 2002. This form can be submitted via the CDMRP web site at http://cdmrp.army.mil/funding/02ocrp1.htm .

IV-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for ITGs. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** The applicant is required to submit Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 18, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the applicant's name (last name, first name, middle initial), and proposal log number. (A proposal log number will be automatically assigned to your proposal when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts

   Please note that the outline found in part 8 of Appendix B does not apply to structured technical abstracts of ITG proposals. Instead, please use the outline below:

   a. Objective: State the objective of the proposed training program.

   b. Program Vision and Goals: State the training program's vision and goals.

   c. Training Program Plan: Briefly describe the training program plan.

   d. Summary of Expertise and Research Areas of Interest: Briefly summarize the qualifications of the Program Director and the training faculty, the scientific emphasis of the program, and the proposed research areas in which postdoctoral trainees will be trained.

   e. Relevance: Provide a brief statement explaining the potential relevance of the proposed training program to ovarian cancer research.

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, ITG proposals shall describe (within the 1-page limit) how the postdoctoral training program will be designed to offer a structured, well-rounded, focused experience in ovarian cancer etiology, prevention, detection/diagnosis, and/or preclinical therapy. Include how the training program will foster the likelihood of its trainees pursuing a career in ovarian cancer research. Indicate how the training program will foster opportunities for collaboration and communication with various members of the training faculty and involvement in other institutional research activities.

11. Proposal Body – See Appendix B, part 11.
The body of ITG proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used.

The body of the proposal should include a clear description of how the postdoctoral training program will draw postdoctoral trainees from different disciplines, all with an underlying interest in ovarian cancer, together into a common environment. The proposal should clearly demonstrate how the training program is different from a mere collection of postdoctoral trainees. ITG proposals should address the following key aspects of the proposed training program: (1) the program vision and goals, (2) the program faculty, (3) the training program and trainees, and (4) the proposed research areas. As part of the discussion of each of these key aspects, the body of the proposal should address:

- the scientific emphasis of the program,
- the proposed research areas in which postdoctoral trainees will be trained,
- how the training program will be structured to integrate ovarian cancer research,
- the training environment and history,
- the physical environment,
- the qualifications of the Program Director,
- the training faculty for postdoctoral programs,
- the selection criteria for postdoctoral trainees,
- the recruitment of trainees into the program, and
- the methods of assigning trainees to a faculty mentor.

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

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.
For ITG proposals, biographical sketches should include a section describing the Program Director's and training faculty members' previous training experiences and mentoring, including experience in the field of ovarian cancer research. A list of significant publications in ovarian cancer research should be incorporated into the biographical sketches. Additionally, biographical sketches for each named trainee must be submitted and included in the Biographical Sketch section.

15. Existing/Pending Support – See Appendix B, part 15.
    A list of current and pending grant support for the proposed faculty mentors must be included in this section.

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

17. Administrative Documentation – See Appendix B, part 17.
    Provide the following items in the Administrative Documentation section.

    Provide a letter of support from the institution indicating a commitment to the postdoctoral training program in the Administrative Documentation section of the proposal submission.

    Note: The signed letter of support from the applicant's institution **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Training awards typically have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. ITGs can be requested for a maximum of $600,000 inclusive of direct and indirect costs over a 3-year period of performance. These funds can cover postdoctoral salary, faculty salary, seminars and courses, administrative support (e.g., photocopying charges, telephone and fax services, secretarial support, etc.), travel to scientific meetings, and limited supplemental funds for research supplies excluding animal purchase. The amount allotted for travel is $1,500 per year per postdoctoral trainee. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests.

19. Instruments – See Appendix B, part 19.

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

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