DEPARTMENT OF DEFENSE

FISCAL YEAR 2001
OVARIAN CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT

March 22, 2001
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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 2001 (FY01) OCRP 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 6 on page iii of this Foreword) also can be downloaded from the CDMRP web site at http://cdmrp.army.mil/funding/default. Information on this program announcement, other program announcements, and the U.S. Army Medical Research Acquisition Activity can be obtained at http://www-usamraa.army.mil.

1. Highlights of Changes from the FY00 Program Announcement

- A single award mechanism, the Program Project Award, is being offered in the FY01 OCRP. Please review Section III carefully as requirements for this award mechanism have changed significantly from previous years.

- As in the FY00 OCRP, this year’s program is encouraging scientific inquiry of epithelial ovarian carcinoma and/or peritoneal carcinoma as related to the following research areas: etiology, early detection/diagnosis, preclinical therapeutics, and quality of life. In addition, two new research areas are being emphasized: prevention and behavioral studies.

- All institutions are eligible to apply. However, preference will be given to institutions that (a) do not have an OCRP Program Project Award, (b) have not been notified that their FY00 Program Project Award submission has been recommended for funding, or (c) have an OCRP Program Project Award nearing completion. (See Section III-A.3.)

- A structured technical abstract using the headings in Appendix B, part 8 is required for all proposals.

- Appendices related to Regulatory Compliance and Quality (Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) have been extensively revised.
2. Who May Apply

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

3. Receipt Deadlines

The proposal receipt deadline is **July 18, 2001 at 4:00 p.m. Eastern Time**. See Appendix B, part 22 for additional details.

4. Timeline

The timeline is:

- **Letter of Intent:** As soon as possible but no later than July 3, 2001
- **Proposal Receipt Deadline:** **July 18, 2001 at 4:00 p.m. Eastern Time**
- **Peer Review:** October 2001
- **Programmatic Review:** January 2002
- **Notification/ Request for RCQ**\(^1\) **Documents:** February 2002
- **Award Negotiations:** Between February 2002 and September 2002

5. 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 (OCRP01)
  1077 Patchel Street (Building 1077)
  Fort Detrick, MD 21702-5024

\(^{1}\) Regulatory Compliance and Quality
Applicants should submit questions regarding this program announcement via e-mail or in writing as early as possible. Every effort will be made to answer questions within 5 working days of receipt.

6. Proposal Cover Booklet (Bubble Sheet)

A Proposal Cover Booklet must be completed for the Overall Program and each Research Project and Core Facility section of a Program Project Award proposal according to the instructions found in Appendix C. 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 (8:00 a.m.-5:00 p.m. Eastern Time)
Fax: 301-682-5521
E-mail: prequest@unitedis.com
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP01)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

7. Proposal Submission

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

Send the Proposal to:
Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (OCRP01)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024
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 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.
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, 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 almost $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, specialty area, or award mechanism. 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 III-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 are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review, which is accomplished by the IP. 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 recommend for funding a broad portfolio of proposals 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;
- Program portfolio balance with respect to research disciplines or specialty areas; and
- Other equitable factors, e.g., 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 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 funding status of his/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 Regulatory Compliance and Quality (RCQ), budget, and Statement of Work. All documents related to RCQ (environmental compliance, human subjects/anatomical substance use, animal use, and safety plan documents) will be requested in the applicant’s notification letter and reviewed by RCQ staff. 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. Therefore, all investigators
submitting such proposals must comply with the requirements detailed in the RCQ documents dealing with research involving laboratory animals and human subjects and/or anatomical substances before funded research can begin.

Concurrent with the RCQ review, a Contract Specialist from the U.S. Army Medical Research Acquisition Activity 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.**

**I-F. 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-G. Publications and Patents**

All investigators are strongly encouraged to publish their results in the scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. 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 to the CDMRP a copy of any manuscript or publication resulting from research funded under the award.

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.

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\(^1\) 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 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 FY01 OCRP.

A summary program history for FY97-00 appropriations of the OCRP is shown in Table II-1 below.

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

<table>
<thead>
<tr>
<th>Program History</th>
<th>FY97-99</th>
<th>FY00</th>
</tr>
</thead>
<tbody>
<tr>
<td>OCRP-Managed Appropriations for Peer-Reviewed Research</td>
<td>$27.5M</td>
<td>$12M</td>
</tr>
<tr>
<td>Number of Full Proposals Received</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Project Award Submissions</td>
<td>222</td>
<td>118</td>
</tr>
<tr>
<td>New Investigator Award Submissions</td>
<td>28</td>
<td>11</td>
</tr>
<tr>
<td>Idea Award Submissions</td>
<td>55</td>
<td>107</td>
</tr>
<tr>
<td></td>
<td>139</td>
<td>N/A1</td>
</tr>
<tr>
<td>Number of Proposals Funded</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Program Project Awards</td>
<td>26</td>
<td>~14</td>
</tr>
<tr>
<td>Investigator-Initiated Research Project</td>
<td>8</td>
<td>~3</td>
</tr>
<tr>
<td>New Investigator Awards</td>
<td>N/A</td>
<td>~1</td>
</tr>
<tr>
<td>Idea Awards</td>
<td>6</td>
<td>~10</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>N/A</td>
</tr>
</tbody>
</table>

1 Not applicable, as this type of award was not offered during this program cycle.
2 Final numbers for FY00 will be available after September 30, 2001.
3 As stated in the FY00 Program Announcement, a Research Project(s) from a Program Project Award submission could be recommended for funding independent from the Program Project Award as a whole.
II-B. Overview of the FY01 OCRP

The USAMRMC, through this program announcement, is requesting proposals 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 building infrastructure and supporting innovative research that will foster new directions for, address neglected issues in, and bring new independent investigators into the ovarian cancer field. The OCRP also encourages proposals 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.

II-C. FY01 OCRP 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 FY01 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, (4) preclinical therapeutics, (5) quality of life, and (6) behavioral studies.

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 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 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.

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, rehabilitation, and genetic counseling.

Behavioral Studies
The OCRP also recognizes the need for behavioral studies in the ovarian cancer field; proposals that address health behavior interventions, psychosocial issues, fundamental mechanisms of cancer-related behaviors, and related topics are encouraged.

II-D. FY01 OCRP Award Opportunities
The programmatic strategy for the FY01 OCRP is to fund Program Project Award proposals (see Section III). The intent of these awards is to enhance ovarian cancer research infrastructure by establishing collaborations in ovarian cancer research across research disciplines and institutions, supporting innovative research, and attracting new independent investigators into the ovarian cancer field. For the FY01 OCRP, an estimated $10.2M will be available to fund competitive peer reviewed research.

Prospective applicants who are familiar with the OCRP requirements from previous years are urged to review this program announcement carefully, as revisions to Program Project Award mechanism definitions and requirements have been made.
# Reference Table of Program Project Award Components and Submission Requirements

The table below summarizes key elements of Program Project Award components and submission requirements. Refer to Section III for further details and proposal preparation instructions. Please note that the proposal receipt deadline is **July 18, 2001 at 4:00 p.m. Eastern Time**.

<table>
<thead>
<tr>
<th>Program Project Components</th>
<th>Experience of Principal Investigator</th>
<th>Key Mechanism Elements</th>
<th>Dollars Available for Individual Awards</th>
</tr>
</thead>
</table>
| **I. Overall Program**    | Investigators with a record of leadership and scientific ability | · To establish new, multidisciplinary programs in ovarian cancer research  
· *Synergistic* program incorporating an Overall Program section, two to four Research Projects, and at least one Core facility  
· To support research in one or more program emphasis areas (etiology, prevention, early detection/diagnosis, preclinical therapeutics, quality of life, and behavioral studies) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma  
· All institutions are eligible to apply. However, preference will be given to institutions that (1) do not have an OCRP Program Project Award, (2) have not been notified that their FY00 Program Project Award submission has been recommended for funding, or (3) have an OCRP Program Project Award nearing completion. (See Section III-A.3.) | A maximum Program Project Award limit of $2.5M, inclusive of direct and indirect costs, over a 2- to 4-year performance period |
| **II. Research Projects** | See Research Project categories below | · A Program Project Award submission **must** include an Idea or New Investigator Research Project. Investigator-Initiated Research Projects may also be included but are not required | See Research Project categories below |
| **A. Idea Research Project** | All levels of experience | · To stimulate and reward creative ideas that may be viewed as speculative, but with the potential for high payoff  
· Presentation of preliminary or pilot data is **not** required | Limited to $300,000 in direct costs over the Program Project Award period |
| **B. New Investigator Research Project (NI)** | · Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer  
· Must have his/her own independent research facilities | · To encourage new investigators to pursue research in the field of ovarian cancer  
· Presentation of preliminary or pilot data is **required** | There is no budget limit for NIs; however, the Program Project Award limit is $2.5M |

(Reference table continued on next page)
## Reference Table of Program Project Award Components and Submission Requirements (cont’d)

<table>
<thead>
<tr>
<th>Program Project Components</th>
<th>Experience of Principal Investigator</th>
<th>Key Mechanism Elements</th>
<th>Dollars Available for Individual Awards</th>
</tr>
</thead>
</table>
| C. Investigator-Initiated Research Project (II) | All levels of experience. | · To sponsor research that will provide insight to the ovarian cancer research field  
· Presentation of preliminary or pilot data is required | There is no budget limit for IIs; however, the Program Project Award limit is $2.5M |
| III. Core Facility(ies) | All levels of experience. | · To provide high quality services required by one or more Research Projects  
· Funding for Core Facilities can be for new Cores specifically focusing on ovarian cancer or for the enhancement of existing Cores | There is no budget limit for Core Facilities; however, the Program Project Award limit is $2.5M |
III. Program Project Awards

III-A. Program Project Awards Overview

The intent of Program Project Awards is to enhance ovarian cancer research infrastructure by establishing collaborations across research disciplines and institutions, supporting innovative research, and attracting new independent investigators into the ovarian cancer research field. Program Projects must be integrated around one or more program emphasis areas (i.e., etiology, prevention, early detection/diagnosis, preclinical therapeutics, quality of life, and behavioral studies) as related to epithelial ovarian carcinoma and/or primary peritoneal carcinoma (see Section II-C). Furthermore, Program Projects should foster collaborations in ovarian cancer research among established and promising investigators. Collaborations between institutions, particularly Historically Black Colleges and Universities and Minority Institutions (HBCU/MI) and non-HBCU/MI, are encouraged.

A strong institutional commitment of resources and space is required. No mechanism is available to provide additional support after the current Program Project Award funding 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 $2.5 million (M), inclusive of direct and indirect costs, over a 2- to 4-year performance period. Please note that clinical trial proposals will not be considered for funding due to the limited availability of funds.

III-A.1 Program Project Award Components

A Program Project Award submission must consist of the following components:

- an Overall Program,
- a minimum of two and a maximum of four Research Projects, and
- a minimum of one Core Facility.

At least one of the Research Projects in a Program Project Award submission must be an Idea or New Investigator Research Project. Investigator-Initiated Research Projects may also be included but are not required (see Section III-A.2 for Research Project category descriptions). In addition, funding for Core Facilities can be for new Cores specifically focusing on ovarian cancer or for the enhancement of existing Cores.
III-A.2 Description of Research Project Categories

_Idea Research Project_

The intent of the Idea Research Project is to stimulate and reward creative ideas that may be viewed as speculative, but with the potential for high payoff. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. The proposed concept may be untested, but have a high probability for revealing new avenues of investigation. The inclusion of preliminary or pilot data is **not** required for Idea Research Projects; however, investigators must demonstrate a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning. Although this type of research is inherently risky in nature, the study plan should demonstrate solid scientific judgment and rationale. An Idea Research Project budget is limited to $300,000 in direct costs over the period of the award.

_New Investigator Research Project_

The intent of the New Investigator Research Project is to encourage new investigators to pursue research in the field of ovarian cancer. Presentation of preliminary or pilot data is required. To qualify, the New Investigator must (1) hold a position of Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer research and (2) have their own independent research facilities. There is no budget limit for New Investigator Research Projects; however, the Program Project Award limit is $2.5M.

_Investigator-Initiated Research Project_

The intent of the Investigator-Initiated Research Project is to sponsor research that will provide insight to the ovarian cancer research field. These Research Projects are intended to fund independent investigators across a broad spectrum of disciplines. Presentation of preliminary or pilot data is required. There is no budget limit for Investigator-Initiated Research Projects; however, the Program Project Award limit is $2.5M.

### III-A.3 Eligible Institutions

The fiscal year 2001 (FY01) Program Projects funding effort is envisioned as a catalyst for a broader national ovarian cancer research enterprise. Consistent with this vision, all institutions are eligible to apply; however, preference will be given to institutions that:

a. do not have an Ovarian Cancer Research Program (OCRP) Program Project Award (note: an individual Research Project funded out of a Program Project proposal does not constitute a Program Project Award);

b. have not been notified that their FY00 Program Project Award submission has been recommended for funding; or
c. have an OCRP Program Project Award nearing completion (i.e., OCRP Program Project Awards that expire before November 30, 2002 based on the original award period of performance).

Proposals from institutions described above will be considered first at programmatic review. All other Program Project proposals will be reviewed and recommended for funding or alternate status only if they are most meritorious and fill a scientific void in the OCRP grant portfolio.

**III-B. Scientific Peer Review Evaluation Criteria for Program Project Award Proposals**

Scientific peer review of Program Project Award 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 Sections III-B.2 and III-B.3. Then, the Overall Program section of the proposal will be evaluated according to the criteria in Section III-B.1.

**III-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:

**Research Plan:** Are scientifically excellent Research Projects and Core Facility(ies) proposed? Is the proposed research innovative? Is the proposed research multidisciplinary? Will the proposed research foster an environment conducive to groundbreaking research in ovarian cancer?

**Synergism:** Are the proposed Research Projects and Core Facility(ies) well integrated? Does this integration result in a synergy that is of greater benefit than the sum of individual research initiatives?

**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?

**Program Project Director and Management Plan:** Does the Program Project Director (i.e., the Principal Investigator [PI] of the Overall proposal) have the training and expertise to oversee the multidisciplinary research of the Program Project? Is there evidence that the Program Project Director has the leadership, experience, and scientific ability to successfully coordinate and lead the proposed Program Project? Has a research 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?
Environment/Institutional Commitment: Have adequate resources been allocated to support the overall research goals of the Program Project? Does the proposal document an institutional research environment supportive of the effort? Is there evidence of a strong institutional commitment to sustain the long-term goals of the effort?

Budget: Is the budget appropriate 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?

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

Research Projects within Program Project Award submissions will be evaluated according to the following criteria:

Research Strategy:
Idea Research Projects: Preliminary or pilot data are **not** required but may be included. 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? If statistical analyses are appropriate, is there a clear statistical plan, including power analysis, outlined in the proposal?

New Investigator and Investigator-Initiated Research Projects: Are the conceptual framework, hypotheses, experimental 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? If statistical analyses are appropriate, is there a clear statistical plan, including power analysis, outlined in the proposal? Do the required preliminary or pilot data relevant to ovarian cancer research support the proposed project?

Scientific Relevance: Does the project address epithelial ovarian carcinoma and/or primary peritoneal carcinoma? To what extent will the project, if successful, make an original and important contribution to advancing research in the field? Does the proposal make a convincing case for the relevance of the research to ovarian cancer?

Innovation:
Idea Research Projects: Does the proposed research represent a new paradigm, challenge existing paradigms, look at an existing problem from a new perspective, develop new methodologies or technologies, or address underexplored or unexplored areas? Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative?

New Investigator and Investigator-Initiated Research Projects: Does the research employ novel
concepts, approaches, or methods? Are the aims original and innovative?

**Personnel:**

*Ideas and Investigator-Initiated Research Projects:* Is the PI well suited to carry out this work? Is there appropriate representation from all the expertise areas needed, including statistical expertise, if appropriate, to conduct the study successfully?

*New Investigator Research Projects:* Is the PI appropriately trained and well suited to carry out this work? Does the PI show potential for becoming a contributing member of the ovarian cancer field? Is there appropriate representation from all the expertise areas needed, including statistical expertise, to conduct the study successfully?

**Environment:** Is there evidence that the scientific environment is appropriate for the proposed research? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?

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

### III-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 the Research Projects and the overall goals of the Program Project? Will the Core Facility provide high quality services required by one or more Research Projects? Is the facility adequate to provide these services?

**Personnel:** Are the 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 Research Project(s)?

**Budget:** Is the budget appropriate for the proposed Core services and functions?

### III-C. Programmatic Review Evaluation Criteria for Program Project 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 this proposal advance the field of ovarian cancer research? How well does the proposal meet the intent of the Program Project Award mechanism?

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.

**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 July 3, 2001. 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/funding/reposit

**III-E. Proposal Preparation**

Refer to Sections III-E.1, III-E.2, and III-E.3 for the specific preparation requirements of each Program Project proposal section. Please note that the proposal receipt deadline is July 18, 2001 at 4:00 p.m. Eastern Time.

**III-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 III-B and III-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.
   All institutions are eligible to apply. However, preference will be given to institutions that (a) do not have an OCRP Program Project Award; (b) have not been notified that their FY00 Program Project Award submission has been recommended for funding; or (c) have an OCRP Program Project Award nearing completion. (See Section III-A.3.)


4. **Proposal Cover Booklet** – See Appendix B, part 4 and Appendix C.
   A Proposal Cover Booklet must be completed for the Overall Program.

5. **Title/Referral Page** – See Appendix B, part 5.
   A Title/Referral 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 III-11 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 PI’s name (last name, first name, middle initial).

   A Checklist for Proposal Submission must be completed for the Overall Program.

   For the Overall Program, provide both a structured technical abstract and a lay abstract 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 technical and lay abstracts.

9. Statement of Work – Only required if budget is requested for the Overall Program.

    A Proposal Relevance Statement must be completed for the Overall Program. The Overall Program proposal section should state explicitly how the proposed work is relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Describe how relevance in the proposal will contribute to research in the field.

    The Overall Program proposal body is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section.

    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 Program Project as a whole. 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 themes and objectives.


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 III-13. 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.

   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.

   In the Overall Program description, include any Facilities/Equipment Description not included within individual Research Projects or Core Facility(ies). Include institutional support (e.g., institutional Core services) on a separate page. Indicate how existing shared or Core services will be accessed and utilized.

   Also include in this section a letter from a Dean, President, or appropriate official describing institutional support for the establishment of a Program Project. Describe any cost sharing or matching funds and plans to continue the program beyond the funding provided by this application as described in the Themes/Objectives section of the proposal body.
   For the Overall Program Cost Estimate, please use the form on page III-15. 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 $2.5M, 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.


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

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# Program Project Awards

**Program Project Director:**  
_____________________________  
Last Name  First Name  MI

**Proposal Title:**  
________________________________________________________________

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## Program Project Award Proposal: Overall Program  
### Table of Contents

<table>
<thead>
<tr>
<th>Page Number</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>i</td>
<td>Proposal Cover Booklet (12 pages)</td>
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<tr>
<td>1</td>
<td>Title/Referral Page (no page limit)</td>
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<tr>
<td>1</td>
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<tr>
<td>2</td>
<td>Checklist for Proposal Submission (1 page)</td>
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<tr>
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<td>Technical Abstract (1-page limit)</td>
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<tr>
<td>4</td>
<td>Lay Abstract (1-page limit)</td>
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<tr>
<td>5</td>
<td>Statement of Work (2-page limit; only required if budget is requested for Overall Program)</td>
</tr>
<tr>
<td></td>
<td>Proposal Relevance Statement (1-page limit)</td>
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<tr>
<td></td>
<td>Proposal Body (10-page limit)</td>
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<td></td>
<td>Abbreviations (1-page limit)</td>
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<tr>
<td></td>
<td>References (no page limit)</td>
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<tr>
<td></td>
<td>List of Participants for the Entire Proposal</td>
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<tr>
<td></td>
<td>Biographical Sketches (3-page limit per individual)</td>
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<td></td>
<td>Program Project Director and other key personnel</td>
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<tr>
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<td>List of all items included in Administrative Documentation Section</td>
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<tr>
<td></td>
<td>Letter confirming institutional support for the establishment of the Program Project</td>
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<tr>
<td></td>
<td>Overall Program Cost Estimate (no page limit)</td>
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<tr>
<td></td>
<td>Instruments (no page limit)</td>
</tr>
</tbody>
</table>
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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 (II¹): 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 (NI²): 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 (Idea³): 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.

¹ II: Investigator-Initiated Research Project
² NI: New Investigator Research Project
³ Idea: Idea Research Project
# Overall Program Cost Estimate Form
(Budget for Entire Proposed Period of Support)

**Principal Investigator (last, first, middle):**

<table>
<thead>
<tr>
<th>Budget Category Totals¹</th>
<th>Overall Program (costs not included in Research Project or Core budgets)</th>
<th>Projects and Cores</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Project 1 (Required)</td>
<td>Project 2 (Optional)</td>
<td>Project 3 (Optional)</td>
</tr>
<tr>
<td>Personnel</td>
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<tr>
<td>Fringe Benefits</td>
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<td></td>
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<tr>
<td>Consultant Costs</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Major Equipment</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Materials, Supplies, and Consumables</td>
<td></td>
<td></td>
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<tr>
<td>Travel Costs</td>
<td></td>
<td></td>
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<tr>
<td>Research-Related Patient Costs</td>
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<td></td>
<td></td>
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<tr>
<td>Other Expenses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subtotal Direct Costs (not including Consortium Costs)</td>
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<td></td>
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<tr>
<td>Consortium Costs</td>
<td>Direct</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Indirect</td>
<td></td>
<td></td>
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<tr>
<td>Total Direct Costs for Entire Proposed Period of Support</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total Indirect Costs for Entire Proposed Period of Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Costs for the Entire Proposed Period of Support²</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

¹ 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.

² The amount should agree with that entered in the Overall Program Proposal Cover Booklet, item #4.
JUSTIFICATION: FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.
III-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 III-B and III-C.

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


4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C. A Proposal Cover Booklet must be completed for each Research Project.

5. Title/Referral Page – See Appendix B, part 5. A Title/Referral Page must be completed for each Research Project.

6. Table of Contents – See Appendix B, part 6. Use the table of contents on page III-21 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 PI’s name (last name, first name, middle initial).


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 relevant to epithelial ovarian carcinoma and/or primary peritoneal carcinoma. Articulate how this relevance will 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. **Presentation of preliminary or pilot data is required for New Investigator and Investigator-Initiated Research Projects.**

For each **Research Project**, describe the proposed research using the general outline provided below:

a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe the major question(s) in ovarian cancer research that is the focus of this proposal. Include information on previous experience most pertinent to the proposal. Cite relevant literature references.

b. **Hypothesis/Purpose:** State the hypothesis to be tested, the purpose of the Research Project, and the expected results and outcomes.

c. **Objectives:** State concisely the specific aims and research strategy of the study. Describe the expected measurable outcomes of the proposed work. Provide information as to how the Research Project will address these objectives and why the approaches are better than traditional collaborations.

d. **Data:** Provide information on well-founded research that supports this project. New Investigator and Investigator-Initiated Research Projects must include data to support the feasibility of the hypotheses and/or approaches.

e. **Proposed Research and Methods:** Describe the experimental plan and methodology that will address the specific research question. 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.


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.


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

Also, for New Investigator Research Projects only, include in this section the Statement of Eligibility form found on page III-23, which 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 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.

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 $2.5M inclusive of direct and indirect costs over a 2- to 4-year performance period. Please note that Idea Research Project budgets are limited to $300,000 in direct costs over the period of the Program Project Award. 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.


23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
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Program Project Director:

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>MI</th>
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</thead>
</table>

Overall Program Title:  

Research Project PI:

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>MI</th>
</tr>
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</table>

Research Project:

Number/Category Acronym/Title

Program Project Award Proposal: Research Project

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Technical Abstract (1-page limit) .......................................................................3
Lay Abstract (1-page limit) ................................................................................4
Statement of Work (2-page limit) .................................................................5
Proposal Relevance Statement (1-page limit) .....................................................
Proposal Body (10-page limit) ...........................................................................
Abbreviations (1-page limit) ...............................................................................8
References (no page limit) ..................................................................................
Biographical Sketches (3-page limit per individual)
  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)
  List of all items included in Administrative Documentation Section..............
  Statement of Eligibility Form (for New Investigator Research Projects only) ....
  Letters of Support and/or Collaboration (as applicable) ................................
Detailed Cost Estimate (no page limit) ..............................................................
Instruments (no page limit) .................................................................................
Program Project Awards

Publications and Patent Abstracts (5-document limit) ..............................................................
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| Name of Applicant: | ___________________________________________________________ |
| Title of Proposal: | ___________________________________________________________ |
| Name of Applicant’s Organization: | ___________________________________________________________ |
| Location of Applicant’s Organization: | ___________________________________________________________ |
| Signature of Applicant: | ___________________________________________________________ |

I certify that the above-named investigator fulfills the requirements to be considered as the Principal Investigator of a Program Project Award New Investigator Research Project and specifically meets the following criteria:

- Holds a position of Assistant Professor or equivalent with no more than 6 years of experience in the field of ovarian cancer, **and**
- Has his/her own independent research facilities.

| Name of Official (please print): | ___________________________________________________________ |
| Title: | ___________________________________________________________ |
| Organization: | ___________________________________________________________ |
| Signature of Official: | ______________________________  Date: ______________ |
Please include the Statement of Eligibility form in the Administrative Documentation section of a New Investigator Research Project proposal.
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III-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 III-B and III-C.

The following proposal preparation information is specific for a Core Facility within a Program Project proposal. Please do not submit proposals for existing Core Facilities for which funds are not being requested. This information should be included in the Facilities/Equipment Description section of the Overall Program or Research Project(s) as appropriate.


4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
   A Proposal Cover Booklet must be completed for each Core Facility.

5. Title/Referral Page – See Appendix B, part 5.
   A Proposal Title/Referral Page must be completed for each Core Facility.

   Use the table of contents on page III-29 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 PI’s name (last name, first name, middle initial).

   A Checklist for Proposal Submission must be completed for each Core Facility.


9. Statement of Work – See Appendix B, part 9 and Appendix D.


   Each Core Facility Proposal Body is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section.
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. 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.

b. Integration: State concisely how the proposed Core Facility will support 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.


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.

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

   Existing Facilities/Equipment Description for the Core Facility should be included within this section.


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 $2.5M, 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.


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

Program Project Director: ______________________________________________________

Last Name  First Name  MI

Overall Program Title: __________________________________________________________

Core Facility PI: ________________________________________________________________

Last Name  First Name  MI

Core Facility: ___________________________________________________________________

Letter/Title

Program Project Award Proposal: Core Facility

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Proposal Relevance Statement (1-page limit) ...............................................___
Proposal Body (10-page limit) .................................................................___
Abbreviations (1-page limit) .................................................................___
References (no page limit) ........................................................................___
Biographical Sketches (3-page limit per individual)
  Core Facility 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)
  List of all items included in Administrative Documentation section ...........___
  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) ....................................___