

PROGRAM ANNOUNCEMENT

DEPARTMENT OF DEFENSE (DOD) OVARIAN CANCER RESEARCH PROGRAM (OCRP)

IDEA DEVELOPMENT AWARD

Funding Opportunity Number: W81XWH-09-OCR-IDA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The OCRP was established in Fiscal Year 1997 (FY97) to promote innovative research focused on eliminating ovarian cancer. Appropriations for the OCRP from FY97 through FY08 totaled \$121.7 million (M). The FY09 appropriation is \$20M.

The overall goal of the FY09 OCRP is to eliminate ovarian cancer by supporting high impact, innovative research. In striving to achieve this goal, the FY09 OCRP is supporting unique partnerships and fostering the next generation of investigators in ovarian cancer.

B. Award Description

The OCRP Idea Development Award mechanism was offered in FY02 through FY06, and in FY08 to support innovative research in ovarian cancer. During this time, 681 applications have been received, and 58 OCRP Idea Development Awards have been granted.

The OCRP Idea Development Award supports high impact, innovative research that will drive the field forward. **NEW FOR FY09** – While this award seeks applications from all areas of ovarian cancer research, for FY09, the OCRP encourages applications that address critical needs of the ovarian cancer community in the following areas:

- Initiation and precursor lesions in ovarian cancer with emphasis on the role of the fallopian tube in disease pathogenesis.
- Molecular understanding of disease heterogeneity.
- Validation of biomarkers for diagnosis, molecular imaging, and therapeutic response.

Applications addressing one of these three Areas of Encouragement will be given primary consideration.

Important aspects of the Idea Development Award are as follows:

- 1. Impact:** The proposed research should have a significant impact on the concepts or methods that drive the field of ovarian cancer research. The proposed research is expected to make original and important contributions to the goal of advancing ovarian cancer research and/or ovarian cancer patient care.
- 2. Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may be innovative in study concept, research methods or technology, clinical interventions, or adaptations of existing methods or technologies.

Research that represents an incremental advance on previously published work is not considered innovative. Examples of research that are not innovative and that will not be considered for funding under this mechanism include: Exploring a previously tested hypothesis in a different cell line; using a published series of in vitro assays to further

characterize a model system; and incorporating known biomarkers into in vitro or clinical models of ovarian cancer.

3. Preliminary Data: Applications must include preliminary data that is relevant to ovarian cancer and the proposed project, but not necessarily in ovarian cancer.

4. (NEW FOR FY09) Optional Nested Teal Predoctoral Scholar: A nested Teal Predoctoral Scholar is being offered as an optional part of the Idea Development Award. The intent of the nested Teal Predoctoral Scholar is to foster the next generation of ovarian cancer investigators through mentored research training of doctoral degree candidates who are committed to a career in ovarian cancer.

- A nested Teal Predoctoral Scholar is defined as a predoctoral student who is currently enrolled full time in an accredited doctoral program (e.g., Ph.D., M.D./Ph.D., D.Sc.) **and** who will successfully complete comprehensive examinations or otherwise meet predissertation requirements by the time of award negotiations.
- Only one (1) predoctoral student can be nested as a Teal Predoctoral Scholar within a given Idea Development Award application. “To be named” Teal Predoctoral Scholars are not allowed for the application submission.
- Applications that contain a nested Teal Predoctoral Scholar will qualify for a higher level of funding as described under the Funding Section (Section I.D).
- A **required Teal Predoctoral Scholar Statement** from the proposed Scholar should:
 - Identify a primary mentor.
 - Articulate career goals and how the proposed research training will promote a career in ovarian cancer research.
- Supporting documentation should include a biographical sketch and three Letters of Support. One letter must be from the Scholar’s primary mentor.
- To qualify for the nested Teal Predoctoral Scholar, all requirements described above must be included in the application. If these requirements are not met or if the nested Teal Predoctoral Scholar does not qualify, then the government reserves the right to review the application as a traditional Idea Development Award.

C. Eligibility

Independent investigators from academia, research institutions, industry, government agencies, and private foundations are eligible to submit applications. Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable direct cost amount for the entire period of performance is \$375,000.

- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

Funding for an Idea Development Award that includes a qualified nested **Teal Predoctoral Scholar:**

- The maximum period of performance is 3 years.
- The maximum allowable direct cost amount for the entire period of performance is \$475,000 if the application includes a qualified nested Teal Predoctoral Scholar.
 - Applications requesting the higher level of funding that do not include a qualified nested Teal Predoctoral Scholar will have their budget reduced as appropriate.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Stipend
- Tuition
- Research supplies
- Equipment
- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot \$8.4M of the \$20M FY09 appropriation to fund approximately 14 applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

Awards that include a clinical trial cannot be transferred to another institution. Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Application submission is a two-step process consisting of (1) pre-application submission and (2) application submission. *Pre-application submission is a required first step.*

- **Pre-application Submission Deadline:** **March 2, 2009, 5:00 p.m. Eastern time (ET)**
- **Invitation to Submit an Application:** **April 7, 2009**
- **Application Submission Deadline:** **June 2, 2009, 11:59 p.m. ET**
- **Scientific Peer Review:** **July 2009**
- **Programmatic Review:** **October 2009**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Application submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). *Applications will not be accepted unless a Principal Investigator (PI) has been invited. Do not submit an application unless a letter of invitation has been received.*

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at: help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications.

A. Step 1 - Pre-Application Components, Submission, and Screening

1. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by *5:00 p.m. ET on the pre-application deadline*. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- **Preproposal Narrative:** The Preproposal Narrative has a *two-page limit* inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the pre-application. The preproposal narrative should address the following:

- **Area of Encouragement:** State which of the three Areas of Encouragement that this application addresses (if applicable).
- **Research Idea:** State the ideas and reasoning on which the proposed work is based and how the application addresses a central problem in ovarian cancer.
- **Research Strategy:** Concisely state the project's objective and specific aims. If applicable, describe the role of the nested Teal Predoctoral Scholar in the proposed project.
- **Impact:** Briefly state how the proposed research will significantly impact the concepts and methods that drive the field of ovarian cancer research and/or ovarian cancer patient care.
- **Innovation:** Describe how the research represents more than an incremental advance on published data.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
 - **References:** List up to five relevant journal references.
 - **Biographical Sketches:** Include biographical sketches for the PI, key collaborators, and the nested Teal Predoctoral Scholar (if applicable).

2. Pre-Application Screening: Pre-applications will be screened by the OCRP Integration Panel, composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** How the application addresses the intent of the award.
- **Research Strategy:** How the specific aims support the research idea.
- **Impact:** What impact these studies will have on the concepts or methods that drive the field.
- **Innovation:** How the research represents more than an incremental advance on published data.

B. Step 2 - Application Components and Submission

PIs will receive notification of invitation to submit an application for the Idea Development Award. Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each application submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 1: Project Narrative (10-page limit)

Describe the proposed research in detail. *The project narrative must include preliminary data that is relevant to ovarian cancer and the proposed project, but not necessarily in ovarian cancer.*

Describe the proposed project using the following outline:

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be supported by this application. If this research project is part of a larger study, present only tasks that the Department of Defense award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms & Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publication URLs and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support
 - Letters of Collaboration (if applicable)
 - Teal Predoctoral Scholar Statement (if applicable) (two-page limit): The proposed Teal Predoctoral Scholar Statement must:
 - Identify the primary mentor
 - Articulate career goals and how the proposed research training will promote a career in ovarian cancer research. Describe qualifications and achievements that make the predoctoral student the ideal candidate for the Teal Predoctoral

Scholar. Describe the potential for a successful career in ovarian cancer research.

- Three Letters of Support for the Teal Predoctoral Scholar (if applicable): If a Teal Predoctoral Scholar is proposed, then three Letters of Support should be provided, including one letter from the primary mentor. Each letter of support should include the qualifications and achievements that qualify this predoctoral student as an ideal candidate for the Teal Predoctoral Scholar. Describe the proposed Teal Predoctoral Scholar's commitment to ovarian cancer research.

- Attachment 3: Technical Abstract
- Attachment 4: Public Abstract
- Attachment 5: Statement of Work (SOW)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement

Explain how the proposed research will have an impact on the concepts or methods that drive the field of ovarian cancer research. Describe how the proposed research will provide original and important contributions to the goal of advancing ovarian cancer research or ovarian cancer patient care.

- Attachment 8: Innovation Statement

Summarize how the proposed research is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

- ***Although not all-inclusive***, the following examples are ways in which the proposed research may be innovative and are intended to help PIs frame the innovative features:
 - Study concept – Investigation of a novel idea and/or research question.
 - Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.
 - Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- Attachment 9: Federal Agency Financial Plan (if applicable)
- Attachments 10-15: Subaward Detailed Budget and Justification (if applicable)

3. Research & Related Senior/Key Person Profile (Expanded Form)

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
 - Teal Predoctoral Scholar Biographical Sketch (if applicable)

- Key Personnel Current/Pending Support

4. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess.htm>.

The peer review and program review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other correcting actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in order of decreasing importance:

- **Impact**
 - If successful, how the proposed research will have an impact on the concepts or methods that drive the field.
 - How the proposed research will provide original and important contributions to the goal of advancing ovarian cancer research and/or ovarian care patient care.
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, and by the

presentation of preliminary data relevant to the project and logical reasoning.

- How well the hypotheses or objectives, experimental design, methods, and analyses are developed, and how well these support completion of the aims.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- **Innovation**
 - How the project proposes new paradigms or challenges existing paradigms.
 - How the proposed research is innovative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
 - How the proposed research represents more than an incremental advance to published data.

The following criteria will not be individually scored, but may impact the overall evaluation of your application:

- **Personnel**
 - The research team's background, experience, and expertise with respect to the proposed work.
 - The appropriateness of the levels of effort by the PI and other key personnel (including, if applicable, the proposed Teal Predoctoral Scholar) to ensure success of the proposed work.
 - If applicable, how the nested Teal Predoctoral Scholar career goals and plans, and the proposed research training will promote a career in ovarian cancer research.
- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **Application Presentation**
 - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism,

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact and innovation, and
- Program portfolio balance, with consideration of the Areas of Encouragement.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel members and recommended for funding to the Commanding General, USAMRMC. The highest scoring applications from the first tier of review are not automatically recommended for funding.

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

1. The following will result in administrative rejection of the pre-application:
 - Preproposal Narrative exceeds page limit.
 - Preproposal Narrative is missing.
 - Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
2. The following will result in administrative rejection of the application:
 - Project Narrative exceeds page limit.
 - Project Narrative is missing.
 - Budget is missing.
 - Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <http://cdmrp.army.mil/research.htm>.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by award mechanism.
- Inclusion of URLs with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Website: <https://cdmrp.org>
Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk, which is available Monday to Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan accordingly, as the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726

Email: support@grants.gov

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.