

PROGRAM ANNOUNCEMENT

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

IDEA DEVELOPMENT AWARD

Funding Opportunity Number: W81XWH-08-OCR-IDA

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I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (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

2. 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. Eastern time.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: help@cdmrp.org

3. 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. Deadlines for proposal submission are 11:59 p.m. Eastern time 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 ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list 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.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and 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 FY07 totaled \$111.7M. The FY08 appropriation is \$10M.

The overall goal of the FY08 OCRP is to eliminate ovarian cancer by stimulating and supporting high impact research as well as unique partnerships and collaborations in ovarian cancer.

B. Award Description

The OCRP Idea Development Award mechanism was offered in FY02 through FY06 to support innovative research in ovarian cancer. During this time, 616 proposals have been received and 51 OCRP Idea Development Awards have been made.

The OCRP Idea Development Award supports high impact, innovative research that will drive the field forward. **NEW FOR FY08** – This award seeks proposals from all areas of ovarian cancer research. However, for FY08, this award encourages proposals that address critical needs of the ovarian cancer community in the following areas:

- Identification and characterization of early changes associated with ovarian cancer.
- Identification and characterization of ovarian cancer stem cells.
- The contribution of the stroma to the tumor microenvironment in ovarian cancer.

Proposals 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: Preliminary data relevant to the proposed project, but not necessarily in ovarian cancer, are required.

4. Proposals Involving Clinical Trials: If a proposal requests support for a clinical trial, the PI is required to submit a clinical protocol in addition to the proposal by the proposal receipt deadline. Such trials must have a clinical coordinator who has sufficient time dedicated to the project to carry out the record keeping, coordination, and/or other administrative duties the project entails. The protocol will be reviewed separately.

Clinical trials must begin within 12 months of the award date. If an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is required, additional time may be granted. However, preference will be given to proposals that have U.S. Food and Drug Administration (FDA) approval at the time the award is made.

5. Optional Non-traditional Collaboration (NEW FOR FY08): The FY08 OCRP Idea Development Award strongly supports collaborative research between an academic institution/government agency and a biotechnology/pharmaceutical company, or between an academic institution/government agency and a foundation, or between a biotechnology/pharmaceutical company and a foundation. The intent of this optional non-traditional collaboration is to increase the leveraging of resources in the ovarian cancer research community. The collaborator in this optional non-traditional collaboration must contribute at least 10% level of effort to the project (as reflected in the budget) and provide intellectual input and research resources (e.g., supplies, reagents, equipment, personnel), or intellectual input and financial resources. Collaborations that bring new perspectives from other disciplines or bring new investigators into the ovarian cancer field are also strongly encouraged. Consequently, if the PI does not have experience in ovarian cancer, then the collaborator must have ovarian cancer experience, as demonstrated through publications in the field, funding history, and/or patient care.

Proposals that contain an optional non-traditional collaboration will qualify for a higher level of funding as described under the Funding Section (Section D). Traditional collaborations between academic institutions are encouraged for this mechanism, but will not qualify for the higher level of funding. ***A required Statement of Optional Non-traditional Collaboration must clearly articulate how the optional non-traditional collaboration leverages resources, and therefore justifies the higher level of funding (see the description above).***

C. Eligibility

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

D. Funding

Funding for an Idea Development Award can be requested for up to \$375,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

Funding for an Idea Development Award that includes a qualified optional non-traditional collaboration can be requested for up to \$450,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

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

- Salary
- Research supplies
- Equipment

- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

The CDMRP expects to allot \$2.8 million (M) of the \$10M FY08 appropriation to fund approximately 4-5 proposals, depending on the quality and number of proposals received. Funding of proposals 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, Appendix 5, for general award administration information.

III. TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time, March 26, 2008
- **Invitation to Submit a Proposal:** April 23, 2008
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, July 2, 2008
- **Peer Review:** September 2008
- **Programmatic Review:** October 2008

Awards will be made approximately 4 to 6 months after receiving the funding notification letter but no later than September 30, 2009.

IV. SUBMISSION PROCESS

Proposal 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) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). *Proposals will not be accepted unless a PI has been invited. Do not submit a proposal unless a letter of invitation has been received.*

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

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

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. Eastern time on the pre-application deadline.** Refer to the Application Instructions for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)

1. 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 preproposal. The preproposal narrative should address the following:

- **Area of Encouragement:** State which of the three Areas of Encouragement that this proposal addresses (if applicable).
- **Research Idea:** State the ideas and reasoning on which the proposed work is based and how the proposal addresses a central problem in ovarian cancer.
- **Research Strategy:** Concisely state the project's objective and specific aims. If applicable, describe how the optional non-traditional collaboration contributes to 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.

2. Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are:

- **References:** List up to five relevant references.
- **Biographical Sketches:** Include biographical sketches for the PI, key collaborators, and the collaborator from the optional non-traditional collaboration (if applicable).

3. 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 proposal 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 - Proposal Components and Submission

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

Each proposal 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. In addition to the specific instructions below, please refer to the Application Instructions 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 inclusion of preliminary data relevant to the proposed project, but not necessarily in ovarian cancer, is required.*

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 proposal.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this proposal is part of a larger study, present only tasks that the DOD 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 and Acronyms
 - Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publication URLs and/or Patent Abstracts (5-document limit)

- Letters of Institutional Support
- Letters of Collaboration (if applicable)
- Statement of Optional Non-traditional Collaboration (if applicable)
 - Describe how the optional non-traditional collaboration fulfills the eligibility requirements and will increase the leveraging of resources in the ovarian cancer research community. Describe the effort of the non-traditional collaborator and the intellectual input and research resources (e.g., supplies, reagents, equipment, personnel) or intellectual input and financial resources being contributed to this optional non-traditional collaboration. Collaborations that bring new perspectives from other disciplines or bring new investigators into the ovarian cancer field are also strongly encouraged. Consequently, if the PI does not have experience in ovarian cancer, then the collaborator must describe his/her ovarian cancer experience, as demonstrated through publications in the field, funding history, and/or patient care.

- Attachment 3: Technical and Public Abstracts
- Attachment 4: Statement of Work (SOW)
- Attachment 5: Impact Statement

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

- Attachment 6: Innovation Statement

Summarize how the proposal is innovative. The following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- 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.

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

- Attachment 7: Clinical Protocol (if applicable)
- Attachment 8: Federal Agency Financial Plan (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)
- Key Personnel Current/Pending Support

4. Research & Related Budget Form

- Budget Justification

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

6. R&R Subaward Budget Attachment(s) Form (if applicable)

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals 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 and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal 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. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal 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 proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals 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 proposals 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 have 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 preliminary data relevant to the project and logical reasoning.
 - How well the hypotheses or objectives, experimental design, methods, and analyses are developed and support completion of the aims.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How the optional non-traditional collaboration contributes to the project and leverages resources (if applicable).
- **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.
- **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 the optional non-traditional collaborator, if applicable) to ensure success of the proposed work.
 - How the optional non-traditional collaborator's experience, expertise, and involvement in the study significantly contributes to the project (if applicable).
- **Environment**
 - How the scientific environment (including collaborative arrangements) is appropriate for the proposed research.
- **Budget**
 - How the budget is appropriate for the proposed research.

2. Clinical Protocol Review Criteria (if applicable)

All clinical trials will be scientifically reviewed according to the following criteria as applicable. The reviewers will evaluate:

- **Trial Design**
 - How the scientific rationale and preliminary data, including critical review and

analysis of the literature, and laboratory and preclinical evidence support the proposed trial and its feasibility.

- How well the aims, hypothesis or objectives, experimental design, methods, data collection procedures, and analyses are developed.
- How the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, and standardization of procedures) are adequate.
- How the recruitment, informed consent, and screening processes for volunteers will be conducted.
- Whether the inclusion, exclusion, and randomization criteria are adequate.
- **Clinical Impact**
 - How this study will affect the treatment and/or management of the disease.
 - How this study will affect the magnitude and scope of potential clinical applications.
- **Intervention, Drug, or Device**
 - The appropriateness of the intervention, drug, or device to be tested in the clinical trial.
 - The availability and purity of the substance to be used in the clinical trial (if applicable).
 - Documentation that an Investigational New Drug/ Investigational Device Exemption has been submitted (if applicable).
- **Feasibility**
 - The feasibility of the proposed clinical study.
 - The plans for addressing unanticipated delays (e.g., slow accrual) and completing the proposed study within the performance period.
 - The availability of volunteers for the clinical trial, the prospect of their participation, and the likelihood of volunteer attrition.
 - The progress toward obtaining local Institutional Review Board approval of the clinical protocol and informed consent form.
- **Statistical Plan (as appropriate for the Phase of study)**
 - How the statistical plan, including sample size projections and power analysis, is adequate for the trial and all proposed correlative studies.
 - The consistency of the data analysis plan with the study objectives.
- **Personnel**
 - How the clinical trial team's background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease, and clinical trials).
 - The appropriateness of the levels of effort for successful conduct of the proposed

work.

- **Environment**
 - The evidence of an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the clinical trial at each participating center.
 - Whether the clinical trial requirements are supported adequately by the accessibility to facilities and resources (including collaborative arrangements).
 - The institutional commitment from each participating institution.
- **Ethics and/or Regulatory Issues**
 - How the ethical considerations, information privacy, and assessment of risks and benefits of participation in the clinical trial will be addressed.
 - The plan for dealing with adverse events, which should include named agencies or offices to be notified in this event, and point of contact information.
 - The plans for data disposition during and after the clinical trial.
 - The procedures for protocol modifications during the course of the study.
 - The plans for data and safety monitoring.
- **Budget**
 - How the budget is appropriate for the proposed clinical trial.

3. Programmatic Review: Criteria used by programmatic reviewers to make funding recommendations that maintain the program’s broad portfolio include:

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

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.

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. *Pre-applications and proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively*

rejected.

The following will result in administrative rejection of the entire pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- FY08 Integration Panel (IP) members are included in any capacity in the pre-application process (excluding references). A list of the FY08 IP members may be found at <http://cdmrp.army.mil>.

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- FY08 IP members are included in any capacity in the proposal, budgets and any supporting document (excluding references). A list of the FY08 IP members may be found at <http://cdmrp.army.mil>.

For any other sections of the pre-application and proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review. Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to include plagiarized information will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.