

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program (OCRP)

Career Development Award, Phase I

Funding Opportunity Number: W81XWH-08-OCRP-CAR

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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 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 \$111.7 million (M). The FY08 appropriation is \$10M.

The overall goal of the FY08 OCRP is to eliminate ovarian cancer by supporting research to detect, diagnose, prevent, and control ovarian cancer.

B. Award Description

The OCRP Career Development Award (*NEW FOR FY08*) is intended to support research training opportunities for investigators wishing to pursue an independent career in ovarian cancer research. This award supports individuals in the early stages of their careers by providing the

opportunity to obtain the funding and experience necessary to pursue an independent career at the forefront of ovarian cancer research.

Key elements of this award include:

- **Principal Investigator:** PIs may be research- or physician-scientists at either the postdoctoral or early-career level. Investigators from Historically Black Colleges and Universities/Minority Institutions are encouraged to apply.
- **Ovarian Cancer Mentorship:** A **designated mentor** is required. This mentor must be an established ovarian cancer researcher; have ovarian cancer funding (past and present); and have a record of ovarian cancer publications in peer reviewed journals. In addition, the mentor must demonstrate a commitment to developing and sustaining the PI's independent research career in ovarian cancer research.
- **Career Development:** The Career Development Plan should be prepared with guidance from the mentor. The proposal should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise to have a career at the forefront of ovarian cancer research. The plan should outline how the PI will be trained in ovarian cancer research. Because career development is the focus of this award, the institution must demonstrate a commitment to the PI through protected time: at least 50% for a research Postdoctoral Fellow PI and at least 25% for the Physician-Scientist PI or Early-Career PI.
- **Research Strategy:** Studies in all areas of ovarian cancer-focused research may be proposed for the Career Development Award; however, research from one of the three areas listed below is encouraged (*NEW FOR FY08*):
 - 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.

Preliminary data relevant to the proposed project, but not necessarily in ovarian cancer, are required. Clinical trials are not allowed under this award mechanism.

The Career Development Award is a Phase I Award. All PIs funded by this award will be encouraged to compete for an independent Phase II award designed to sustain independent ovarian cancer researchers. It is anticipated that the Phase II award will be offered in FY11, pending availability of Federal funds for this program.

C. Eligibility

Eligibility for the Career Development Award:

- **Postdoctoral Fellow Level:** At the time of submission, must have completed a doctoral degree and have a total of less than 5 years of postdoctoral research experience (excluding clinical residency or fellowship training).

- **Early-Career Investigator Level:** At the time of submission, must be within 3 years of having completed postdoctoral, fellowship, or other post-graduate training, and must have received less than \$300,000 in direct costs in aggregate for ovarian cancer research as a PI of Federally or privately funded, non-mentored, peer reviewed grants.

Refer to Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for the Career Development Award for the Postdoctoral Fellow can be requested for up to \$300,000 in direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

Funding for the Career Development Award for the Early-Career Investigator can be requested for up to \$375,000 in 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
- Health insurance
- Research supplies
- Equipment
- Clinical costs
- Tuition for training and/or other educational opportunities
- Consultation with scientific and/or technical experts (e.g., statisticians, editors)
- Travel to scientific/technical meetings
- Travel between collaborating institutions

Salary support for the designated mentor is not allowed.

The CDMRP expects to allot approximately \$3.3M of the \$10M FY08 OCRP appropriation to fund approximately six Career Development Award proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. Award Administration

Changes in PI will only be allowed in extenuating circumstances and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met. A change in the mentor is discouraged. 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 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 the 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](https://cdmrp.org/) 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

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).
- **PI's Career Goals:** Describe the PI's career goals and a demonstrated commitment to pursuing an independent research career at the forefront of ovarian cancer.
- **Career Development:** Briefly describe the plan of the overall professional development of the PI and how it will prepare the PI for an independent career in ovarian cancer research.
- **Research Project:** State the ideas and reasoning on which the proposed work is based and how the proposed work addresses a problem in ovarian cancer.

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 and designated mentor (four-page limit per individual).
- **Designated Mentor's Letter: Two-page limit.** The designated mentor should provide a letter that addresses the following:
 - The mentor's research expertise in ovarian cancer.
 - The mentor's success in acquiring funding in ovarian cancer research.
 - The mentor's experience in mentoring students, postdoctoral fellows, and early-career investigators.
 - The mentor's and his or her staff's commitment to the PI's professional development through this award.

3. List of Three Individuals Providing Letters of Recommendation: Two-page limit per letter. The PI must request confidential letters of recommendation from three individuals through the CDMRP eReceipt system by entering their names and contact information into the appropriate data fields. Each individual will receive an email generated from the CDMRP eReceipt system containing specific instructions on how to upload their letter.

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

- **PI's Career Goals:** How the PI's career goals are consistent with a commitment to pursue a career as an ovarian cancer researcher.
- **Career Development:** How the Career Development Plan will contribute to the overall professional development of the PI.

- **Research Project:** How well the research project will allow the PI to develop expertise needed for an independent career in ovarian cancer research.
- **Designated Mentor:** How the mentor's research experience, funding history, and track record in mentoring investigators for a career in ovarian cancer research indicates the potential for successful mentorship and development of the PI as an independent investigator.

B. Step 2 - Proposal Components and Submission

PIs will receive notification of invitation to submit a proposal for the Career Development Award. Proposals will not be accepted unless the 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 through [Grants.gov](http://www.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 project in detail using the outline below. *Proposals must include preliminary data relevant to the proposed project.*

- **PI's Past Accomplishments and Career Goals:** Describe the PI's career goals and a demonstrated commitment to pursuing an independent research career at the forefront of ovarian cancer. Outline the PI's record of accomplishments and how they demonstrate his or her potential for contributing to the field of ovarian cancer research and completing the proposed project. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed work.
- **Career Development Plan:** Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to have a career at the forefront of ovarian cancer research, including but not limited to courses, workshops, laboratory or clinical techniques, conferences, seminars, or journal clubs, and grant writing skills development. The Career Development Plan should include a description of the overall professional development of the PI and how it will prepare the PI for an independent career in ovarian cancer research. The Plan should outline how the PI and mentor will evaluate the PI's progress of becoming an independent investigator. The Career Development Plan should be composed with guidance from the mentor and should be consistent with the PI's research goals.

- **Research Project:** 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. The research description should also describe the ability of the PI to conduct the research or the relevant training that will be obtained to accomplish the project. ***This award may not be used to conduct clinical trials.***
- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publications and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support (two-page limit per letter)
 - Letters of Collaboration (if applicable, two-page limit per letter)
 - Designated Mentor's Letter: Two-page limit. This letter must:
 - Discuss the PI's background and potential to become an independent ovarian cancer researcher.
 - Explain how this award will enhance the PI's research capabilities in ovarian cancer.
 - Demonstrate the mentor's research expertise in ovarian cancer and success in acquiring funding in ovarian cancer research, as well as mentoring students, postdoctoral fellows, and early-career investigators.
 - Specify the commitment of the mentor and his or her staff to the PI's professional development through this award.
 - Describe the specific resources provided by the mentor that will facilitate successful completion of the training and research project.
 - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical and Public Abstracts (one-page limit per abstract)
 - Please note that these abstracts should include specific elements (including career development plan, research plan, and impact). Refer to the Application Instructions for detailed information.
- Attachment 4: Statement of Work (two-page limit)
- Attachment 5: Impact Statement (one-page limit)

Demonstrate how the proposed research and Career Development Plan will facilitate the PI's transition into an independent career at the forefront of ovarian cancer research. Describe how the proposed research makes an original and important

contribution to the goal of advancing ovarian cancer research and/or ovarian care patient care.

- Attachment 6: Eligibility Statement
- Attachment 7: Federal Agency Financial Plan (if applicable)

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
 - Include designated mentor's Biographical Sketch
- Key Personnel Current/Pending Support
 - Include designated mentor's 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)

7. Three Confidential Letters of Recommendation (two-page limit per letter)

Three individuals listed by the PI to provide confidential letters of recommendation in the pre-application will receive an email generated from the CDMRP eReceipt system containing specific instructions on how to upload their letters. The PI should monitor receipt of these letters; however, the PI will not be able to view the letters. *All confidential letters of recommendation must be submitted through the CDMRP eReceipt system by 5:00 p.m. Eastern time, July 2, 2008.*

The letters of recommendation must be submitted by the individuals named in the pre-application. If this is not possible, the PI must contact the CDMRP eReceipt help desk for assistance.

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.htm>.

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of 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., Impact Statement or designated mentor's letter).

B. Review Criteria

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

- **Principal Investigator**
 - How the PI's record of accomplishments demonstrates his or her potential for contributing to the field of ovarian cancer research and completing the proposed project.
 - How the mentor's letter and letters of recommendation from others support the PI's potential for a productive and independent career in ovarian cancer research.
 - How the PI's career goals are consistent with a commitment to pursuing a career as an ovarian cancer researcher.
 - Whether the level of effort of the PI meets the requirements (at least 50% for a research Postdoctoral Fellow PI; at least 25% for the Physician-Scientist PI; at least 25% effort for the Early-Career PI), and is appropriate for successful conduct of the proposed work and putting the PI on the path to an independent career focused on ovarian cancer research.
 - Whether the PI meets the appropriate eligibility requirements.
- **Career Development Plan**
 - How well the PI has outlined an individualized Career Development Plan that is consistent with the PI's research goals.

- How the Career Development Plan will contribute to the overall professional development of the PI and prepare the PI for an independent career at the forefront of ovarian cancer research.
- Adequacy of the plans for evaluating the PI's progress of becoming an independent investigator.
- **Designated Mentor**
 - How the mentor's background, research experience, and funding history support the PI's career development needs and transition to independence.
 - How the mentor's track record in preparing investigators for careers in ovarian cancer research indicates the potential for successful mentorship and development of the PI as an independent investigator.
 - Whether the quality of the Career Development Plan and research project suggests that the mentor provided appropriate guidance.
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the research project and its feasibility as demonstrated by a review and analysis of the literature and relevant preliminary data.
 - How well the hypotheses or objectives, experimental design, methods, and analyses are developed and support completion of the aims.
 - How well the research project will allow the PI to develop expertise needed for an independent career in ovarian cancer research.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Impact**
 - How the proposed research and Career Development Plan will foster the PI's transition into an independent career in ovarian cancer research.
 - How the proposed research makes an original and important contribution to the goal of advancing ovarian cancer research and/or ovarian cancer patient care.
- **Research Resources**
 - How the proposed research project and career development of the PI is supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.
 - Whether there are clear commitments from the institution and the mentor.
- **Budget**
 - How the budget is appropriate for the proposed research.

2. Programmatic Review: Criteria used by the IP to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact,
- 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 the IP 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 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 involve any allegation of research misconduct 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.