PROGRAM ANNOUNCEMENT

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program (OCRP)

Consortium Development Award

Funding Opportunity Number: W81XWH-08-OCRP-CONDEV

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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/) 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 through 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 should also be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's 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 stimulating and supporting high impact research as well as unique partnerships and collaborations in ovarian cancer.

B. Award Description

The OCRP Consortium Development Award mechanism is **NEW FOR FY08**.

The OCRP seeks to promote a major multi-institutional research effort conducted by leading ovarian cancer researchers that ***specifically focuses on identifying and characterizing early changes of disease associated with ovarian cancer***. This effort will be executed through two separate award mechanisms, the Consortium Development Award in FY08 and the Consortium Award in FY10.

Proposals for the first award, the Consortium Development Award, are being requested in this program announcement. The Consortium Development Award is an infrastructure development mechanism which provides support to create a Coordinating Center and establish the necessary collaborations at potential Research Sites to develop a multi-institutional ovarian cancer research team. Participants in this consortium should be scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to the early changes associated with ovarian cancer progression. Infrastructure development includes (but is not limited to): building appropriate collaborations, outlining an administrative management plan, developing a research and communication plan, and devising an intellectual property plan. ***The FY08 Consortium Development Award does not provide funding for research costs.*** However, recipients of the FY08 OCRP Consortium Development Award are expected to submit proposals to compete for the Consortium Award which will be offered in FY10 to support the research efforts. The OCRP expects to fund two FY08 Consortium Development awards, depending on the number and the quality of proposals received. If this goal is met, then OCRP expects that only these two FY08 Consortium Development award winners will compete for the FY10 Consortium Award. If this goal is not met, then we reserve the right to open the FY10 Consortium Award to all applicants meeting the eligibility requirements.

The consortium should include a Coordinating Center and Research Sites. The Coordinating Center, in addition to functioning as a Research Site, should serve as the consortium's information and planning nexus providing administrative, operational, and data management support services to participant Research Sites. The Coordinating Center should have extensive experience in developing and conducting multi-institutional research projects. Responsibilities of the Coordinating Center will include protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, intellectual/material

property coordination, and a plan for assessment of individual Research Site performance. All Research Sites will be responsible for working collaboratively. The Consortium Director, i.e., the principal investigator (PI) on the proposal, should have a proven track record of leadership and scientific ability to direct and oversee the overall research effort.

FY10 Consortium Award Description: A description of the scope and intent of the FY10 Consortium Award is provided at this time to assist investigators in preparing proposals for the FY08 Consortium Development Award. The FY10 Consortium Award supports research focused only on the identification and characterization of the early changes of disease associated with ovarian cancer**.** The scope of this research effort may include a broad spectrum of research spanning from preclinical to clinical studies with the end result leading to a significant understanding of the early changes of disease associated with ovarian cancer. The consortium should comprise a multi-institutional research team made up of scientists and/or clinicians who have made significant contributions in the field of ovarian cancer or who have specific expertise related to the early changes associated with ovarian cancer. It is expected that named research sites will be included in the full consortium award. Any changes should be fully justified. Collaborations established through the consortium should be synergistic. The Consortium should maximize the use of resources and minimize unnecessary duplication among consortium members; e.g., experimental techniques, databases, models, animal models, antibodies, etc. should be shared resources for all consortia members. The OCRP Integration Panel and members of CDMRP will serve as an external advisory board for the consortium. ***There is no guarantee that funds will be available for the FY10 Consortium Award.***

C. Eligibility

PIs must be independent investigators at the Assistant Professor level (or equivalent) or higher. Refer to the Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for the Consortium Development Award can be requested for up to $150,000 for direct costs for up to a 1-year performance period, plus indirect costs as appropriate.

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

- Salary
- Meetings and teleconferences among participating investigators to develop the consortium, including applicable travel costs
- Other costs associated with planning and developing the consortium collaborations and resources

The CDMRP expects to allot approximately $0.45M of the $10M FY08 OCRP appropriation to fund approximately two Consortium Development Awards, 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

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, June 25, 2008**
- **Proposal Submission Deadline: 11:59 p.m. Eastern time, July 9, 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/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/).

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 and Submission

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.

1. Proposal Information
2. Proposal Contacts
3. Collaborators and Conflicts of Interest (COI)
4. Letter of Intent (LOI) Narrative

B. Step 2 – Proposal Components and Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. 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 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 qualifications of the consortium members and plans for the development of key features of the consortium using the following general outline:

     - Provide a description of the projected consortium organization. Include key participants at the Coordinating Center and the Research Sites, and their projected contributions. Named Research Sites should submit a letter of collaboration. Describe previous experience and accomplishments of the PI (Consortium Director) related to the design, administration, and management of multi-institutional research projects.

     - Describe the management and communication plan for developing the consortium. Include plans for assessing the performance of each research site.

     - Describe the overall approach the consortium will use to have a significant impact on the identification and characterization of the early changes associated with ovarian cancer. Include a brief description of the available resources and how unnecessary duplication of resources among consortium members will be minimized. Include an estimated duration and the projected direct costs that would be required to answer this critical research question.

   - **Attachment 2: Supporting Documentation**
     - References Cited
     - Acronyms and Symbol Definitions
     - Publications and/or Patent Abstracts (Five-document limit.)
     - Letters of Collaboration (Two-page limit per letter. Required.): Provide a signed letter from each of the proposed research site collaborators that describes how he

or she will support the PI and the consortium, and will resolve intellectual and material property rights.

- **Attachment 3: Technical and Public Abstracts (1-page limit per abstract.)**
- **Attachment 4: Statement of Work (2-page limit.)**
- **Attachment 5: 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; include biosketches for collaborators at each Research Site.)
   - 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.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.

B. Review Criteria

Peer Review: All proposals will be evaluated according to the following criteria, which are of equal importance.

Consortium Structure

Whether the consortium includes a Coordinating Center and Research Sites with named scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to early changes associated with ovarian cancer progression.

How well the infrastructure includes building appropriate collaborations, outlining an administrative management plan, developing a research and communication plan, and devising an intellectual property plan.

How well it is shown that the Coordinating Center and Research Sites will maximize the use of resources and minimize unnecessary duplication of resources.

How well plans for assessing the performance of each Research Site are outlined.

Personnel

How well the PI's (Consortium Director) qualifications and experience demonstrate appropriate expertise in the design, organization and management of multi-institutional research projects.

How the consortium team's background and expertise are appropriate to accomplish the goal of understanding early changes associated with ovarian cancer.

How well the consortium participants are committed to developing a consortium to address the identification and characterization of early changes associated with ovarian cancer.

Impact

How effectively the consortium structure and overall approach will lead to the identification and characterization of early changes in ovarian cancer.

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, 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 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 or 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 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 Integration Panel (IP) members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at http://cdmrp.army.mil/ocrp/panel08.htm.

For any other sections of the pre-application or 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.