PROGRAM ANNOUNCEMENT

DEPARTMENT OF DEFENSE (DOD)

OVARIAN CANCER RESEARCH PROGRAM (OCRP)

COLLABORATIVE TRANSLATIONAL RESEARCH AWARD

Funding Opportunity Number: W81XWH-09-OCRP-CTR

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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 Collaborative Translational Research Award is new for FY09. It is similar to the Translational Research Partnership Award that was offered in FY07 and FY08 to support partnerships between clinicians and laboratory scientists to conduct translational research in ovarian cancer.

The key initiative of the Collaborative Translational Research Award is to encourage ***multi-institutional, multi-disciplinary*** collaborations among clinicians and laboratory scientists that accelerate the movement of promising ideas in ovarian cancer into clinical applications. This award is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to make a major impact on ovarian cancer.

NEW FOR FY09 – The Collaborative Translational Research Award <u>ONLY</u> accepts applications from these three Areas of Emphasis:

- Initiation and precursor lesion 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

The Collaborative Translational Research Award supports the development of translational research collaborations among **three or four** independent investigators (known as partners) to address one of the three areas of emphasis in ovarian cancer in a manner that would be less readily achievable through separate efforts. At least one partner must be a clinician, and at least one partner must have experience either in ovarian cancer research or ovarian cancer patient care. It should be clear that all partners have equal intellectual input into the design of the research project. Historically Black Colleges and Universities/Minority Institutions are encouraged to apply**.** A proposed project in which one of the partners merely supplies tissue samples or access to patients will not meet the intent of this mechanism.

Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and anecdotal data. The ultimate goal of translational research is to move an observation forward into the clinical application. The

Collaborative Translational Research Award supports preclinical studies in animal models and human subjects and human anatomical substances, Phase 0 and Phase I clinical trials, correlative studies that are associated with an existing clinical trial, and projects that develop clinical endpoints for clinical trials. Developing the research plan must involve a reciprocal flow of ideas and information within the research team. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at (http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals). These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials.

This award mechanism is not intended to support the study of new combinations of conventional ovarian cancer therapies. The use of existing resources is encouraged, including libraries of compounds or probes, tissue repositories such as those managed by the Gynecologic Oncology Group, and other existing sets of tissue, blood, or images.

Important aspects of the Collaborative Translational Research Award are as follows:

1. **Collaboration:** The success of the project depends on the unique skills and contributions of each collaborator. Of the three to four partners, at least one partner must be a clinician, and at least one partner must have experience either in ovarian cancer research or ovarian cancer patient care.

2. **Translational:** The application should provide evidence for the reciprocal transfer of ideas between basic and clinical science in developing and implementing the research plan.

3. **Multidisciplinary:** Proposals should emphasize a ***multidisciplinary program*** in which two or more ***major*** disciplines are integrated into the research team environment. ***It is the responsibility of all of the Principal Investigators (PIs) to clearly and explicitly articulate how the proposed disciplines are distinct and necessary for this research.*** For this award, major disciplines include, but are not limited to:

    - Basic biological (including pathology)
    - Clinical
    - Chemical
    - Imaging
    - Social and behavioral
    - Engineering, physical, and mathematical sciences
    - Public health and health services research

4. **Multi-institutional:** At least two distinct institutions must be involved.

5. **Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising ideas in ovarian cancer into clinical applications.

6. Preliminary Data: Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to come from the ovarian cancer research field.

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

Each collaborative partner will be a PI, and a separate award will be made to each partner's institution. The PIs are expected to be equal partners in the research, and the direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

- The maximum period of performance is 3 years.
- The maximum allowable funding for the entire period of performance is $375,000 in direct costs per PI.
- 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 the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

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

- Salary
- 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 $2.0M of the $20M FY09 OCRP monies to fund approximately 1 Collaborative Translational Research Award application, depending on the quality and number 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 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/) and (2) an application submission through Grants.gov (http://www.grants.gov/). ***Applications will not be accepted unless a 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 Collaborative Translational Research Award is structured to accommodate three or four PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PIs will be identified as the Partnering PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute to the preparation of the proposal. ***The Initiating PI must complete the pre-application process and submit contact information for each Partnering PI.***

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

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

1. Pre-application Components for the Initiating PI

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:** The Initiating PI must enter the Application Information before continuing the pre-application.
- **Proposal Contacts:** The Initiating PI must enter his/her contact information.
- **Partners and Conflicts of Interest (COI):** The Initiating PI must enter the contact information for the collaborating PIs in the "Partnering PIs" section.
- **Preproposal Narrative:** The Preproposal Narrative has a ***three-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preapplication. The Preproposal Narrative should address the following:
    - **Area of Emphasis:** State which of the three Areas of Emphasis this application addresses.
    - **Research Idea:** State the ideas and reasoning on which proposed research is based. Show how the perspective of each team member contributes to the development of the idea.
    - **Research Strategy:** Concisely state the project's objective and specific aim.
    - **Collaboration:** Describe how the project incorporates multiple disciplines and how it depends on the unique skills of each partner. Provide the time commitment for each partner as well. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
    - **Translational:** Describe the reciprocal transfer of ideas between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications in ovarian cancer.
    - **Impact:** State explicitly how the proposed research will have an impact on accelerating the movement of a promising idea in ovarian cancer into clinical applications.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
    - **References Cited:** List up to five relevant references.
    - **Biographical Sketches:** Include biographical sketches for all partners and other key collaborators.

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 Strategy:** How the specific aims support the research idea.
- **Collaboration:** How the partners' backgrounds and expertise are appropriate to accomplish the proposed research that could not be accomplished by either a single investigator or through separate efforts. Appropriateness of the proposed disciplines and the levels of effort.
- **Translational:** How the project will translate promising, well-founded research findings into clinical applications in ovarian cancer.
- **Impact:** How the study addresses an important problem related to one of the three areas of emphasis in ovarian cancer. If successful, how the collaboration and the aims of the application are likely to accelerate the movement of promising ideas in ovarian cancer into clinical applications.

B. Step 2 - Application Components and Submission

PIs will receive notification of invitation to submit an application for the Collaborative Translational Research Award. Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless the Initiating and Partnering PIs receive a letter of invitation. If invited to submit an application, the Partnering PIs will be contacted via e-mail by the CDMRP eReceipt system and provided the information necessary to begin application submission through Grants.gov. Please note that the Partnering PIs must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

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 CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting their application to Grants.gov, each Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system. ***Each PI also must submit an identical copy of a jointly created Statement of Work (SOW).***

1. **Application Submission Components for the Initiating PI**

   - **SF-424 (R&R) Application for Federal Assistance Form**
   - **Attachments Form**
     - Attachment 1: Project Narrative (12-page limit). The Project Narrative is the main body of the application and should demonstrate that a translational research collaboration either exists or will be developed to address one of the three areas of emphasis in ovarian cancer.
     - Describe the proposed research in detail. ***Applications must include preliminary data to support the feasibility of the research hypotheses and research approaches; however, these data do not necessarily need to come from the ovarian cancer research field.***

     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. If this application 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.

       The Collaborative Translational Research Award supports preclinical studies in animal models and human subjects and human anatomical substances, Phase 0 and Phase I clinical trials, correlative studies that are associated with an existing clinical trial, and projects that develop clinical endpoints for clinical trials.
     - **Collaboration:** Describe how the project incorporates multiple disciplines and depends on the unique skills of each partner. Provide the time commitment for each partner as well. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational collaboration will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.

- 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)
- 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 make original and important contributions towards the goal of advancing ovarian cancer research or ovarian cancer patient care.
- Attachment 8: Translatability Statement

  Describe the translational research that will be performed through this award, and articulate why it could not be achieved through separate efforts. State explicitly how the proposed research will translate promising, well-founded research findings into clinical applications in ovarian cancer.
- Attachment 9: Federal Agency Financial Plan (if applicable)
- Attachments 10-15: Subaward Detailed Budget and Justification (if applicable)

2. 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

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

4. Application Components for the Partnering PIs

Before submitting the proposal application to Grants.gov, the Partnering PIs must associate themselves with the proposal by accepting the link sent by the CDMRP eReceipt system. The CDMRP eReceipt system assigns a unique and separate log number which must be used when submitting the Grants.gov application package.

The application submission process for the Partnering PIs uses an abbreviated application package of forms and attachments from Grants.gov. Each Partnering PI will be contacted via email by the CDMRP eReceipt system and provided with the information necessary to begin application submission through Grants.gov. Please note that each Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

The Partnering PIs package includes:

- **SF-424 (R&R) Application for Federal Assistance Form**
- **Attachments Form**
  - Attachment 5: SOW: The Initiating and Partnering PIs must create a joint SOW.
  - Attachment 6: Detailed Budget and Justification
  - Attachment 9: Federal Agency Financial Plan (if applicable)
  - Attachments 10-15: Subaward Detailed Budget and Justification (if applicable)
- **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

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 nondisclosure 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 corrective 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 programmatic 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:

- **Collaboration**
  - Whether all PIs meet the eligibility requirements.
  - How the proposal addresses one of the three Areas of Emphasis in a way that could not be accomplished by a single investigator.
  - Evidence that all partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.
  - How the multiple disciplines and multiple institutions within the collaboration support the proposed project.
  - How the partners' background, expertise, and levels of effort support the proposed project.
- **Translational Potential**
  - How the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for patients with or populations at risk for ovarian cancer
- **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, relevant preliminary data, and logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How the partners acknowledge potential problem areas and consider alternative approaches.
- **Impact**
  - If successful, how the collaboration and the aims of the study project will eventually move from a clinical observation, a laboratory discovery, or population-based study into clinical applications.
  - How the proposed research will have an impact on the concepts or methods that drive the field of ovarian cancer research.

- How the proposed research will make original and important contributions towards the goal of advancing ovarian cancer research or ovarian cancer patient care.

- **Research Resources**
  - How well the partners plan to maximize use of existing resources and avoid unnecessary duplication of effort.
  - The appropriateness of the scientific/clinical environment for the proposed research.
  - Where applicable, evidence of a plan to resolve intellectual and material property issues between collaborating institutions.

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

- **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 Emphasis.

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 (IP) members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. 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
- 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 the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

- At least one partner is not a clinician, or at least one partner does not have experience either in ovarian cancer research or ovarian cancer patient care.

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 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 application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to the Grants.gov help desk, which is available Monday through Friday from 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note the CDMRP help desk is unable to answer questions regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Grants.gov will notify Principal Investigators (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 on 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.