PROGRAM ANNOUNCEMENT

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

TRANSLATIONAL RESEARCH PARTNERSHIP AWARD

Funding Opportunity Number: W81XWH-08-OCRP-TRP

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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 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 Translational Research Partnership Award was first offered in FY07 to support partnerships between clinicians and laboratory scientists to conduct translational research in ovarian cancer. During this time, 22 proposals were received for the Translational Research Partnership Award, and 5 were recommended for funding.

The key initiative of the Translational Research Partnership Award is to encourage partnerships between clinicians and laboratory scientists that accelerate the movement of promising ideas in ovarian cancer into clinical applications. This award supports the development of translational research collaborations between two independent investigators to address a central problem or question in ovarian cancer in a manner that would be less readily achievable through separate efforts. One partner in the collaboration must be a laboratory scientist and the other must be a clinician, and it should be clear that both have had equal intellectual input into the design of the research project. At least one member of the partnership must have experience either in ovarian cancer research or ovarian cancer patient care. Historically Black College and Universities/Minority Institutions are encouraged to apply**.** A proposed project in which the clinical partner 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 first hand knowledge of patients and anecdotal data. While the ultimate goal of translational research is to move an observation forward into the clinical application, members of the partnership should view translational research as a two-way continuum between bench and bedside. Developing the research plan must involve a reciprocal flow of ideas and information within the partnership. 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. Please be aware that ***the Translational Research Partnership Award does not support clinical trials***, but may support correlative studies that are associated with an existing clinical trial and projects that develop clinical endpoints for clinical trials. Research projects may also include preclinical studies in animal models and human subjects and human anatomical substances.

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 FY08 –*** The Translational Research Partnership award accepts proposals from all areas of research, but encourages research from these Areas of Encouragement:

- 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.

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 Translational Research Partnership Award are as follows:

1. Partnership: The success of the project depends on the unique skills and contributions of each partner.

- **Optional Non-traditional Partnership (*NEW FOR FY08*):** This award encourages a partnership 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 partnership is to leverage resources in the ovarian cancer research community. It is expected that in addition to providing intellectual input, the optional non-traditional partnership will contribute research resources (e.g., supplies, reagents, equipment, personnel) and/or financial resources.

2. 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.

3. 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 be in ovarian cancer.

C. Eligibility

Independent investigators from academia, research institutions, industry, government agencies, and private foundations are eligible to submit proposals.

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

D. Funding

Each partner will be a PI, and a separate award will be made to each partner's institution. The combined total funding for both awards can be requested for up to $750,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate. 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 combined total funding for a Translational Research Partnership Award that includes a qualified optional non-traditional partnership can be requested for up to $825,000 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 $2.5 million (M) of the $10M FY08 OCRP monies to fund approximately 2 Translational Research Partnership 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 on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions, Appendix 5, for Administrative 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/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/). ***Proposals will not be accepted unless a PI has been invited. Do not submit a proposal unless the Initiating and Partnering PIs receive an invitation to submit a proposal.***

The Translational Research Partnership Award is structured to accommodate two PIs. Initiating and Partnering PIs each have different submission requirements; however, both PIs should

contribute equally to the preparation of the pre-application and proposal submission. ***The Initiating PI must begin the pre-application process and submit contact information for the Partnering PI.*** If invited to submit a proposal, the Partnering PI will be contacted via email by the CDMRP eReceipt system and provided the information necessary to begin proposal submission through Grants.gov. Please note that the Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his or her grant application package with that of the Initiating PI.

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

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. Eastern time on the pre-application deadline***. In addition to award-specific information provided below, refer to the Application Instructions for detailed information.

- **Proposal Information:** The Initiating PI must enter the Proposal Information before continuing the pre-application.
- **Proposal Contacts:** The Initiating PI must enter his/her contact information.
- **Collaborators and Conflicts of Interest (COI):** The Initiating PI must enter the contact information for the Partnering PI in the "Partnering PI" 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 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 proposed work is based. Show how the perspective of each partner contributes to the development of the idea.
    - **Research Strategy:** Concisely state the project's objective and specific aim.
    - **Partnership:** Describe how the project depends on the unique skills of each partner. Provide the time commitment for each partner as well. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
        - If this proposal includes an Optional Non-traditional Partnership, describe the non-traditional partnership and what it contributes to the proposed work. Please see the Award Description for the optional non-traditional partnership qualifications.

- **Impact:** State explicitly how the proposed work 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:** One-page limit.
  - **Biographical Sketches:** Include biographical sketches for the Initiating PI, Partnering PI, 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.
- **Partnership:** How the partners' backgrounds and expertise are appropriate to accomplish the proposed work that could not be accomplished by either a single investigator or through separate efforts. Appropriateness of the levels of effort for successful conduct of the proposed work is also important.
- **Impact:** How the study addresses an important problem related to ovarian cancer. If successful, how the partnership and the aims of the application are likely to accelerate the movement of promising ideas in ovarian cancer into clinical applications.

B. Step 2 - Proposal Components and Submission

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

The Initiating and Partnering PIs will each be assigned a unique and separate proposal log number by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using his/her unique log number. The PI and Organization identified in the proposal 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.

Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

For contractual reasons, the CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. Each PI must submit an identical copy of a joint SOW. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

1. Proposal Submission Components for the Initiating PI

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/funding opportunity.

The Initiating PI package includes:

- **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 proposal and should demonstrate that a translational research partnership between a laboratory scientist and a clinician either exists or will be developed to address a central problem or question in ovarian cancer. ***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 Idea:** State the hypothesis to be tested. Present the ideas and reasoning behind the proposed work. Describe the intellectual contribution of each member of the partnership to the development of the research idea.
  - **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.

    Observations may be derived from a laboratory discovery, population-based studies, or a clinician's first hand knowledge of patients and anecdotal data. Translational research should be viewed as a two-way continuum between bench and bedside. The process of moving an observation forward into clinical application should involve a reciprocal flow of ideas and information within the partnership. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism can 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. ***The***

Translational Research Partnership Award does not support clinical trials, but may support correlative studies that are associated with an existing clinical trial and projects that develop clinical endpoints for clinical trials.

- **Partnership:** Describe how the research project depends on the unique skills and contributions of each member of the partnership. Provide the time commitment of each partner toward the proposed research project. Describe how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational partnership will maximize the use of existing resources and minimize unnecessary duplication. If partners are from different institutions, 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 and 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 Partnership (if applicable): (One-page limit). For proposals incorporating an optional non-traditional partnership and requesting the higher level of funding, describe how this partnership 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 will leverage resources in the ovarian cancer research community to accelerate the movement of promising ideas in ovarian cancer into clinical applications. Describe what research resources (e.g., supplies, reagents, equipment, personnel) and/or financial resources will be brought to the research project in addition to intellectual input through this non-traditional partnership.
- Attachment 3: Technical and Public Abstracts
- Attachment 4: Statement of Work (SOW): The Initiating and Partnering PIs must create a joint SOW.
- Attachment 5: Impact Statement: State explicitly how the proposed work will have an impact on accelerating the movement of a promising idea in ovarian cancer into clinical applications.
- Attachment 6: Federal Agency Financial Plan (if applicable)

- **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
- **Research & Related Budget Form** (each PI should submit a unique and separate budget and budget justification)
    - Budget Justification
- **Research & Related Project/Performance Site Location(s) Form**
- **R&R Subaward Budget Attachment(s) Form (if applicable)**

2. Proposal Components for the Partnering PI

Before submitting the proposal application to Grants.gov, the Partnering PI must associate him or herself 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 proposal submission process for the Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov.

The Partnering PI package includes:

- **SF-424 (R&R) Application for Federal Assistance Form**
- **Attachments Form**
    - Attachment 4: SOW: The Initiating and Partnering PIs must create a joint SOW.
    - Attachment 6: Federal Agency Financial Plan (if applicable)
- **Research & Related Budget Form**
    - Budget Justification
- **Research & Related Project/Performance Site Location(s) Form**
- **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 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).

B. Review Criteria

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

- **Partnership**
  - Whether both PIs meet the eligibility requirements.
  - How the proposal addresses a central problem or question in ovarian cancer in a way that could not be accomplished by a single investigator.
  - Evidence that both partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.
  - How the partners' expertise and levels of effort support the proposed project.
- **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**
  - How the study addresses an important problem related to ovarian cancer.
  - If successful, how the partnership and the aims of the study project will eventually move from a clinical observation, a laboratory discovery, or population-based study into clinical applications.
- **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 participating institutions.
- **Budget**
  - How the budget is appropriate for the proposed research.

2. 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,
- 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 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.
- Any Budget and/or budget justification is 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 an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.