Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Synergistic Translational Leverage Award

Funding Opportunity Number: W81XWH-12-OCRP-STLA Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Submission Deadline: 5:00 p.m. Eastern time (ET), April 17, 2012
- Invitation to Submit an Application: May 2012
- **Application Submission Deadline:** 11:59 p.m. ET, July 18, 2012
- **Peer Review:** September 2012
- **Programmatic Review:** November 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Ovarian Cancer Research Program (OCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. Appropriations for the OCRP from FY97 through FY11 totaled \$180.45 million (M). The FY12 appropriation is \$16M. The overall goal of the FY12 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.

B. Award Information

The OCRP Synergistic Translational Leverage Award mechanism supports the partnership between *two* Principal Investigators (PIs; termed "partners") who will leverage existing human-based ovarian cancer resources in translational research to address high-impact research ideas or unmet needs in ovarian cancer. Many ovarian cancer resources are confined to investigators' labs where they were first developed and are not always available for use by others. Often, resources are not leveraged for maximum use beyond the original source, and as a result, investigators expend time and money to duplicate those resources. These existing resources are expensive to generate, maintain, and make available to other investigators, but they may have broad applicability across many different types of research questions. Examples of human-based resources include, but are not limited to, biorepositories of clinical specimens, existing tissue banks, epidemiological resources, clinical databases, large transcriptome or proteome datasets, and databases of clinical data and/or metadata.

The Synergistic Translational Leverage Award supports translational projects such as, but not limited to, resource refinement, in silico research, database mining, applied biomarker research, correlative studies, prospective studies involving human subjects, and other translational research. Funds may be requested to support a research project in its entirety or pilot work that will eventually lead to a more comprehensive effort. 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/researchandfunding/trwg/pathways-to-clinical-goals. These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials. *Preliminary data are required. Note that clinical trials can be supported by this award mechanism*.

Leveraging and synergy are important aspects of the Synergistic Translational Leverage Award. It is the responsibility of the PIs to explain how the proposed research leverages an existing human-based ovarian cancer resource and why the resource is uniquely suited to answer the research question. The PIs must also describe the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts.

For the FY12 OCRP, *leveraging is defined as* an investigator basing a research project on existing resources in order to amplify potential gains in knowledge of ovarian cancer, and then making the results or outcomes available for use by others. Thus, it is expected that the results from the Synergistic Translational Leverage Award will be shared with the ovarian cancer community (research, survivor, and advocacy). In addition, the outcomes from this research will be made available via the Congressionally Directed Medical Research Programs (CDMRP) website.

The CDMRP intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

Research efforts demonstrating *synergy* are those that will significantly advance a project in a way that could not be accomplished through independent efforts. Each partner will be recognized as a PI, submit a separate application, and receive an individual award. However, the research project must be supported by the complementary expertise, experience, and abilities of both PIs. The application should clearly demonstrate that both PIs have an equal level of intellectual input into the proposed project and clearly define the synergistic components that will facilitate and accelerate progress. Examples of collaborations that are not considered synergistic include reagents supplied by one PI and molecular studies completed by the other PI; service function or core support providing laboratory investigations or statistical analyses; or projects that can be accomplished in a single PI's laboratory.

NEW FY12 Areas of Encouragement: The Synergistic Translational Leverage Award accepts applications from all areas of ovarian cancer research, but *encourages* research from the following areas:

- Using novel approaches for improving the performance and validity of predictive disease markers
- Understanding the mechanistic basis of disease markers
- Generating novel imaging/molecular imaging approaches for screening and management
- Generating innovative insights in etiology, risk factors, and outcomes for ovarian cancer
- Identifying and validating molecular targets for therapy

OCRP Definition of Disease Marker: A disease marker is a molecular signature, risk factor, or physiological characteristic that associates with the presence, prognosis, or therapeutic response of ovarian cancer.

C. Eligibility Information

- Each PI must be at or above the level of Assistant Professor (or equivalent) to be eligible to submit an application.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable *combined* direct costs for the entire period of performance are \$500,000 for the Initiating PI and Partnering PI, plus indirect costs as appropriate.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- A separate award will be made to each PI's organization.
- The two PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- Maintenance and distribution of resources and outcomes
- Development of software, databases, websites, and/or other information technology
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately \$3.75M of the \$16M FY12 OCRP appropriation to fund approximately five Synergistic Translational Leverage Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

The Synergistic Translational Leverage Award mechanism is structured to accommodate two PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact

information for the Partnering PI. The Partnering PI will then be notified separately by email, and *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*. If an application is invited, only the Initiating PI will receive notification of invitation via email from the CDMRP.

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-12-OCRP-STLA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Initiating PI through the CDMRP eReceipt System (https://cdmrp.org/). Because the invitation to submit an application is based on the contents of the pre-application, the title or research objectives should not be changed after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- Application Information Tab 1
- Application Contacts Tab 2
- Collaborators and Conflicts of Interest (COI) Tab 3

FY12 OCRP Integration Panel (IP) members should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or

1-301-682-5507.

The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

Required Files – Tab 4

Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The Preproposal Narrative should include the following:

- **Research Question:** Describe the research question and explain why it fills an unmet need or a high-impact research opportunity in ovarian cancer within the continuum of translational research.
- Synergy: Describe how the combined efforts are centered on leveraging the
 existing human-based resource and how the PIs will work together to achieve that
 objective from different perspectives.
- Resource: Describe the existing human-based resource that will be leveraged, and why this resource is uniquely suited to answer the research question. Explain how basing a research project on this existing resource will amplify gains in knowledge of ovarian cancer. Describe how the results of this research effort will be shared with the ovarian cancer research and consumer advocacy communities to maximize leveraging.
- **Impact:** Explain how the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer, including the potential short-term and long-term impact.

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

- References Cited (one-page limit)
- Key Personnel Biographical Sketches (four-page limit per individual)

• Submit Pre-Application – Tab 5

This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

Other Documents Tab

No additional documents are required.

Pre-Application Screening

• Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DoD) and the OCRP, pre-applications will be screened based on the following criteria:

- How the proposed translational research question fills an unmet need in or has a high impact in ovarian cancer.
- How well the proposed study represents a synergistic partnership that will produce results greater than those of the PIs working independently.
- How the existing human-based resource will be leveraged to address the proposed research question.
- How the results will be shared with the ovarian cancer research and consumer advocacy communities to maximize leveraging.
- How the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer, including short-term and long-term impact.

• Notification of Pre-Application Screening Results

Following the pre-application screening, Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

Pre-application notification dates are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the Initiating PI has received notification of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). For the Synergistic Translational Leverage Award, additional application components are also required and should be submitted as directed below.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for the Initiating PI:

Grants.gov application package components: For the Translational Synergistic Leverage Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

• Attachment 1: Project Narrative (eight-page limit): Upload as "ProjectNarrative.pdf."

The Project Narrative page limit applies to text and any figures, table, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. *Preliminary data are required*. Describe the proposed project in detail using the outline below.

 Background: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Explain why the proposed research question fills an unmet need or a high-impact research opportunity in ovarian cancer within the continuum of translational research. Describe the existing human-based resource that will be leveraged and why this resource is uniquely suited to answer the research question. Explain how basing a research project on this existing resource will amplify gains in knowledge of ovarian cancer. Explain how the results of this research effort will be shared with the ovarian cancer research and consumer advocacy communities to maximize leveraging and how making the results publically available will remove barriers in future ovarian cancer research or patient care.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be attained.
- Specific Aims: Concisely explain the project's specific aims to be supported by this application. If this research project 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. *Include specific examples of synergistic elements incorporated into the research design*. Address potential problem areas and present alternative methods and approaches.
 Projects using human subjects or human anatomical samples must include a detailed plan for the recruitment of subjects or the acquisition of samples.
- Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable),
 signed by the Department Chair or appropriate organization official, reflecting
 the laboratory space, equipment, and other resources available for the project.
 - Letters of Collaboration (if applicable): Provide a signed letter from each

- collaborating individual or organization that will demonstrate that each PI has the support or resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."
 - Background: State the research question and present the ideas and reasoning behind the proposed work. Describe the resource that will be leveraged and why this human-based resource is uniquely suited to answer the research question. Explain how the proposed research effort is synergistic and how it will significantly advance a project in a way that could not be accomplished through independent efforts.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Describe the study design including appropriate controls.
 - Impact: Explain how the research addresses an unmet need in or has a high impact on ovarian cancer that will ultimately accelerate the movement of promising ideas toward clinical applications, including the short-term and longterm impact.
- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

Lay abstracts should be written using the outline below:

- Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
 - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research, including the short-term and long-term impact:
 - Which individuals will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a clinically relevant result?
 - What are the likely contributions of this study to advancing the field of research?
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.

Both PIs must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.

- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf."
 Describe in detail why the proposed research effort should be supported, focusing
 on how it addresses an unmet need or a high impact on translational research in
 ovarian cancer, the expected outcomes, and anticipated benefits to ovarian cancer.
 Explain how the research will accelerate the movement of promising ideas toward
 clinical applications in ovarian cancer, including the potential short-term and long term impact.
- Attachment 7: Synergy Statement (one-page limit): Upload as "Synergy.pdf." Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs. Describe the contributions of each PI in the proposed effort. Describe how the combined efforts are centered on leveraging the existing human-based resource and how the PIs will work together to achieve that objective from different perspectives resulting in a level of productivity that is greater than that achievable by each PI working independently. Describe the PIs' histories of synergistic and collaborative study with one another and/or with other investigators.
- Attachment 8: Data and Research Resources Sharing Plan (two-page limit): Upload as "SharingPlan.pdf." Describe how data and resources generated during the performance of the project will be shared with the research and consumer advocacy communities. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publically available.
- **3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
 - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
 - Include biographical sketches for both the Initiating and Partnering PI.
 - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - o Include current/pending support for both the Initiating and Partnering PI.
- **4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed \$500,000.

- **5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- **6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

Application Components for the Partnering PI:

The Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for the Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. SF 424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 5: SOW (three-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.
- **3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed \$500,000.

- **4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- **5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

All submission dates and times are indicated on the <u>title page</u> of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD and OCRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure 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. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of decreasing importance:

Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility, as demonstrated by a review and analysis of the literature, the preliminary data, and logical reasoning.
- How well the hypotheses or objectives, experimental design, methods, and analyses have been developed and how well they support completion of the aims.

• How well the PIs identify potential problems and address alternative approaches

Resource Leveraging

- The extent to which this existing human-based resource is uniquely suited to answer the research question.
- How the research requirements are supported by the availability of and accessibility to facilities and resources including the proposed existing humanbased resource to be leveraged.
- How the results of this research effort will be shared with the ovarian cancer research and consumer advocacy communities to maximize leveraging.
- How making the results publically available will potentially remove barriers in future ovarian cancer research or patient care.

Synergy

- To what degree the proposed partnership between the two PIs is likely to result
 in a level of productivity that is greater than that achievable by each PI working
 independently.
- How the project addresses a single translational research project rather than a set of unrelated subprojects.
- To what degree the contributions of each PI to the overall synergy of the project are appropriately balanced.

Impact

- How the proposed research question fills an unmet need in or has high impact on translational research in ovarian cancer.
- How well the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer, including the potential short-term and long-term impact.

Personnel

- The extent to which each PI possesses the research experience necessary to function as a PI in a synergistic project.
- How the research team's background, experience, and expertise are appropriate to execute the proposed work.
- How the levels of effort for each of the two PIs and other key personnel are appropriate for successful conduct of the proposed work.

In addition, the following unscored criteria will contribute to the overall evaluation of the application:

Environment

- How the scientific environments are appropriate for the proposed research.
- How the quality and extent of institutional support are appropriate for the proposed research.

Budget

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- How appropriately the resources are divided between both PIs.

• Application Presentation

- To what extent the writing, clarity, and presentation of the application components influenced the review.
- **2. Programmatic Review:** To determine the application's relevance to the mission of the DoD and OCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:
 - Ratings and evaluations of the peer reviewers
 - Programmatic relevance
 - Relative impact on ovarian cancer
 - Relative synergy
 - Program portfolio balance
 - Adherence to the intent of the award mechanism

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

• Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of an application for which a letter of invitation was not received.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY12 OCRP IP member is named as being involved in the research proposed or is found to have assisted 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 FY12 OCRP IP members can be found at http://cdmrp.army.mil/ocrp/panels/panels12.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1. Upload Supporting Documentation		
	(Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
Attachments Form	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Synergy Statement (Synergy.pdf) as Attachment 7.		
	Upload Data and Research Resources Sharing Plan (SharingPlan.pdf.) as Attachment 8.		
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.		
Senior/Key Person Profile (Expanded)	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.		