

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Translational Leverage Award

Funding Opportunity Number: W81XWH-11-OCRP-TLA

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), June 8, 2011
- **Invitation to Submit an Application:** July 2011
- **Application Submission Deadline:** 11:59 p.m. ET, August 18, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** December 2011

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Ovarian Cancer Research Program (OCRP) was established in 1997 to provide support for research of exceptional scientific merit focused on eliminating ovarian cancer. Appropriations for the OCRP from FY97 through FY10 totaled \$160.45 million (M). The FY11 appropriation is \$20M. The overall goal of the FY11 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.

B. Award Information

The OCRP Translational Leverage Award mechanism supports the leveraging of 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. This award mechanism is focused on leveraging existing human-based resources that will ultimately benefit ovarian cancer research. 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, laboratory expertise, large transcriptome or proteome datasets, and databases of clinical data and/or metadata.

For the FY11 OCRP, *leveraging is defined as* an investigator basing a research project on borrowed or shared 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.

It is the responsibility of the Principal Investigator (PI) to explain how the proposed research leverages an existing resource and why the resource is uniquely suited to answer the research question. Outcomes from the Translational Leverage Award will be made available to the scientific community via the Congressionally Directed Medical Research Programs website. However, the PI should describe how the outcomes from this research will be shared with the ovarian cancer community, making this research effort not just another research collaboration.

The Translational Leverage Award supports translational projects such as, but not limited to, resource refinement, in silico research, database mining, applied biomarker research, correlative studies, 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/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. *Clinical trials are supported with this award mechanism. Preliminary data are required.*

Innovative research projects with translational applications that do not leverage resources do not meet the intent of this Translational Leverage Award mechanism and should be submitted to the FY11 OCRP Translational Pilot Award.

C. Eligibility Information

- Investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit applications.
- 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 direct costs for the entire period of performance are **\$500,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- 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.
- 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.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs may be requested for (not an all-inclusive list):

- Salary
- Research supplies
- Equipment
- Research costs
- Clinical research costs
- Maintenance and distribution of resources and outcomes
- Development 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 Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$4.0M of the \$20M FY11 OCRP appropriation to fund approximately 5 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/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to 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-11-OCRP-TLA.

B. Pre-Application Submission Content and Form

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

PIs and organizations identified in the application should be the same as those identified in the contact information of the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 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**
- **Required Files – Tab 4**

Preproposal Narrative (3-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.
- **Statement of Problem:** Describe why the lack of availability of the existing resource is an obstacle to ovarian cancer research and/or patient care. Explain how leveraging this existing resource will allow the proposed research question to be addressed.
- **Resource:** Describe the existing resource that will be leveraged. Explain why this resource is uniquely suited to answer the research question. Describe how the outcomes of this research effort will be shared with the ovarian cancer community, making this research effort not just another research collaboration.
- **Impact:** Explain how the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer.

Pre-Application Supporting Documentation (one-page limit)

- **Justification of Proposed Cost:** State the estimated budget for the proposed research. Explain how the expected outcomes and anticipated benefits to ovarian cancer justify the proposed cost. This justification is not the typical budget justification submitted with a research application. Do not itemize costs.
- **Submit Pre-Application – Tab 5**
- **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 CDMRP, 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.
 - Whether the lack of availability of this existing resource is an obstacle to ovarian cancer research and/or patient care and how the resource will be leveraged to address the proposed research question.
 - How the outcomes will be shared with the ovarian cancer community to maximize leveraging, making this research effort not just another research collaboration.
 - How the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer.
 - How the leveraging of the resource, the expected outcomes, and the anticipated impact on ovarian cancer justify the proposed costs.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified via email as to whether or not they are invited to submit an application; 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 [title page](#) of this Program Announcement/Funding Opportunity

C. Application Submission Content and Form

PIs will be notified if they are invited to submit an application for the Translational Leverage Award. Applications will not be accepted unless the PI has received an 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 (AOR) through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the Translational 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 in or has a high impact on translational research in ovarian cancer. Describe the existing resource that will be leveraged. Describe why the lack of availability of the existing resource is an obstacle to ovarian cancer research and/or patient care. Explain why this existing resource is uniquely suited to answer the research question. Explain how the outcomes of this research effort will be shared with the ovarian cancer community to maximize leveraging of the shared existing resource, making this research effort not just another research collaboration.

- **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. Address potential problem areas and present alternative methods and approaches. Using human subjects or human anatomical samples requires 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. *Each component has no page limit unless otherwise noted.*
 - **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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they 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 (two-page limit per letter):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. From collaborators providing the leveraged existing resource, describe the source of the resource and how it will be made available to the PI, and the collaborator’s role in the research effort.
 - **Intellectual and Material Property Plan:** Provide a plan for resolving intellectual and material property issues among participating investigators or organizations (if the leveraged resource is from another organization).

- **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, why this resource is uniquely suited to answer the research question, and how leveraging it will allow you to address an unmet need or high-impact research opportunity in translational research in ovarian cancer.
 - 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.

- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
The public abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

Public 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:
 - 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 outcome?
 - 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.
- **Attachment 6: Impact Statement (one-page limit):** Describe why this research effort should be supported, focusing on the expected outcomes and anticipated benefits to ovarian cancer, and how the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer.

3. Research & Related Senior/Key Person Profile (Expanded) Form: 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.”
 - Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
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.”
 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.

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall 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, US Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DOD and CDMRP, 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, it is a crime for Federal officials to disclose confidential information of one party to another third party (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 listed in decreasing importance.

- **Research Strategy and Feasibility**

- How the proposed research question fills an unmet need in or has high impact on translational research in ovarian cancer.
- How the scientific rationale supports the project and its feasibility, as demonstrated by a review and analysis of the literature.
- 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 PI identifies potential problems and addresses alternative approaches.
- How preliminary data support the proposed research.
- How the research requirements are supported by the availability of and accessibility to facilities and resources including the proposed leveraged resource.

- **Resource Leveraging**

- The extent to which the lack of availability of this resource is an obstacle to ovarian cancer research and/or patient care.
- The extent to which this resource is uniquely suited to answer the research question.
- Adequacy of the plan for how the resource will be obtained and made available for this research project.
- How the outcomes of this research effort will be shared with the ovarian cancer community to maximize leveraging of the shared existing resource, making this research effort not just another research collaboration.

- **Impact**

- How well the research will accelerate the movement of promising ideas toward clinical applications in ovarian cancer.

- How the expected outcomes and anticipated impact on and benefits to ovarian cancer justify this research effort being supported.

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

- **Personnel**

- How the research team's background, experience, and expertise are appropriate to execute the proposed work.
- How the levels of effort by the PI and other key personnel will ensure success of the proposed work.

- **Environment**

- How the scientific environment is 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.

- **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 CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Programmatic relevance
- Relative impact on ovarian cancer
- 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 [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. PIs 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 an application for which a letter of invitation was not received.

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, you 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:

- FY11 OCRP IP member 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 FY11 OCRP IP members may be found at <http://cdmrp.army.mil/ocrp/panels/panels11.shtml>.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

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 US 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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

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

The transfer of an award involving a clinical trial to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the Grants Officer.

E. Pre-Award Meeting

At the Government's discretion, if a clinical trial is proposed, the PI and Clinical Study Coordinator may be requested to participate in a pre-award meeting.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and 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	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	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 Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	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.	