

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Ovarian Cancer Research Program

### Clinical Translational Leverage Award

Funding Opportunity Number: W81XWH-14-OCRP-CTLA

Catalog of Federal Domestic Assistance Number: 12.420

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 3, 2014
- **Invitation to Submit an Application:** July, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, August 27, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, September 2, 2014
- **Peer Review:** October 2014
- **Programmatic Review:** December 2014

***Change for Fiscal Year 2014:*** The CDMRP eReceipt System has been replaced with the Electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

***This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov***

## TABLE OF CONTENTS

<b>I. Funding Opportunity Description.....</b>	<b>3</b>
A. Program Description .....	3
B. Award Information.....	3
C. Eligibility Information .....	5
D. Funding .....	5
<b>II. Submission Information .....</b>	<b>6</b>
A. Where to Obtain the Application Package.....	7
B. Pre-Application Submission and Content Form .....	7
C. Application Submission Content and Forms .....	10
D. Verification of Grants.gov Application in eBRAP .....	15
E. Submission Dates and Times .....	15
F. Other Submission Requirements.....	15
<b>III. Application Review Information .....</b>	<b>16</b>
A. Application Review and Selection Process.....	16
B. Application Review Process .....	16
C. Recipient Qualification .....	18
D. Application Review Dates .....	18
E. Notification of Application Review Results .....	18
<b>IV. Administrative Actions.....</b>	<b>19</b>
A. Rejection .....	19
B. Modification.....	19
C. Withdrawal.....	19
D. Withhold .....	20
<b>V. Award Administration Information.....</b>	<b>20</b>
A. Award Notice .....	20
B. Administrative Requirements .....	20
C. National Policy Requirements .....	20
D. Reporting.....	20
E. Award Transfers.....	20
<b>VI. Agency Contacts.....</b>	<b>21</b>
A. CDMRP Help Desk.....	21
B. Grants.gov Contact Center.....	21
<b>VII. Application Submission Checklist.....</b>	<b>22</b>

## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2014 (FY14) Ovarian Cancer Research Program (OCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The OCRP was initiated in FY97 to provide support for research of exceptional scientific merit. Appropriations for the OCRP from FY97 through FY13 totaled \$216.45 million (M). The FY14 appropriation is \$20M. The overall goal of the FY14 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research. The OCRP's long-term priorities are:

- Understand precursor lesion/stem cell, microenvironment, and pathogenesis/progression of all types of ovarian cancer including rare subtypes;
- Develop or improve performance and reliability of screening, diagnostic approaches, and treatment;
- Develop and validate models to study initiation and progression of ovarian cancer;
- Address issues in primary prevention and survivorship;
- Investigate tumor response to therapy including tumor survival, dormancy, cell death, clonal evolution, tumor heterogeneity; and
- Enhance the pool of ovarian cancer scientists.

### B. Award Information

The intent of the OCRP Clinical Translational Leverage Award mechanism is to support leveraging of human-based ovarian cancer resources in translational research. This award supports early-phase, proof-of-principle clinical trials and correlative studies (retrospective and prospective) to investigate high-impact research ideas or unmet needs in ovarian cancer. Preliminary data are required.

- **Leveraging:** For the FY14 OCRP, leveraging involves addressing research questions using existing resources to amplify potential gains in knowledge of ovarian cancer, and subsequently making the results or outcomes available for use by others. Outcomes from research funded by this award are expected to provide data and scientific rationale for future research that will impact ovarian cancer clinical care.
- **Human-Based Resources:** Examples of human-based resources include, but are not limited to, biorepositories of clinical specimens, annotated cell lines, epidemiological datasets, clinical databases, large transcriptome/proteome/metabolomic datasets, and databases of clinical data and/or metadata.

***Funding from the Clinical Translational Leverage Award must support a clinical trial or a correlative study associated with an ongoing or completed clinical trial.***

**Clinical Trials:** The Clinical Translational Leverage Award supports clinical trials encompassing Phase 0 or Phase I, or other types of trials that conduct early clinical testing for

ovarian cancer. Information on clinical trials and phases/classes of study is provided in the “Human Subject Resource Document” available for download from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

**Correlative Studies:** The Clinical Translational Leverage Award also supports correlative studies that derive from ongoing or completed clinical trials supported by other funding sources. Examples of correlative studies appropriate for submission may include, but are not limited to:

- Using clinical trial-related human-based resources to better define tumor subtypes, predict therapeutic response, or assess prognosis by correlating the information with the patient outcome
- Correlating clinical trial-related tissue samples or epidemiological data with clinical outcome
- Prospectively evaluating an exploratory or translational endpoint
- Supporting a secondary aim/goal of a clinical trial by measuring target engagement by a novel therapeutic

It is the responsibility of the PI to clearly articulate how the proposed study addresses a high-impact research idea or unmet need in ovarian cancer.

Important aspects of submission to the Clinical Translational Leverage Award:

- The proposed intervention or correlative study must be based on sound scientific rationale that is established through logical reasoning, critical review and analysis of the literature, and preliminary data.
- If applicable, the application must include documentation of an existing Investigational New Drug (IND) or Investigational Device Exemption (IDE).
- The application must demonstrate availability and accessibility of the appropriate human subject population or human-based resources and provide a detailed statistical analysis plan that includes a power analysis reflecting sample size projections that will support a meaningful outcome.

**Use of Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

*The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 L.*

### **C. Eligibility Information**

- The 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.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

- The maximum period of performance is **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$250,000** plus indirect costs. More cost-effective studies that do not request the full available funding amount are encouraged.
- 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.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. *For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.*

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Research-related subject costs
- Clinical trial costs

- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Tuition

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Extramural investigators are defined as all those not included in the definition of intramural investigators. As required of all applicants to this Program Announcement, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.*** Refer to Appendix 4 of the General Application Instructions for additional information.

***The CDMRP expects to allot approximately \$0.8M of the \$20M FY14 appropriation to fund approximately two Clinical 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 two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

**New for FY14:** *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's

representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

**Note:** Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

#### **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-14-OCRP-CTLA.

#### **B. Pre-Application Submission and Content Form**

All pre-application components must be submitted by the PI through eBRAP (<https://ebrap.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 pre-application should be the same as those intended for the subsequent application submission. A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@ebrap.org](mailto:help@ebrap.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP 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**

- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 OCRP Integration Panel (IP) members should not be involved in any pre-application 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@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Required Files – Tab 4**

*Notes: Files for all of these components must be submitted in PDF format unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

**Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research; include relevant literature citations and preliminary studies that led to the development of the proposed clinical trial and/or correlative study. For a clinical trial, clearly describe the intervention and its target and mechanism of action in ovarian cancer. If the proposed study is correlative to an ongoing or completed clinical trial, describe the relationship between the intervention and the question(s) to be studied.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Study Design:** Describe the design of the clinical trial or research approach for correlative studies. The description should include:
  - The type of study to be performed (e.g., phase/class, prospective, randomized, controlled, correlative, etc.) and proposed methodology.
  - The study variables and proposed measurement.
  - The research team’s capabilities in conducting clinical trials, including discussion of key coordinating activities.
  - The evidence that a sufficient number of subjects or samples are available for the study to obtain statistically significant information.
  - The feasibility of initiating the clinical or correlative study within 6 months of the award date. Note: Invited applications must provide proof of an existing IND/IDE, if applicable.

- How the results of the research effort will be shared with the ovarian cancer research and consumer advocacy communities to maximize sharing and leveraging.
- **Clinical 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 *must be uploaded as individual files*, and are limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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 used in the Preproposal Narrative.
- PI Biographical Sketch (four-page limit): Include a biographical sketch for the PI only.
- **Submit Pre-Application – Tab 5**  
This tab must be completed for the pre-application to be accepted and processed.

## Pre-Application Screening

- **Pre-Application Screening Criteria**

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

- **Intent of the Award Mechanism:** To what degree the proposed translational research question fills an unmet need in or will have a high impact on ovarian cancer. How the results will be shared with the ovarian cancer research and consumer advocacy communities to maximize sharing and leveraging.
- **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible, will accomplish the objectives, and is based on sound scientific rationale.
- **Impact:** How well 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, 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 weakness) on their pre-application. The estimated timeframe

for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### C. Application Submission Content and Forms

***Applications will not be accepted unless the 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/>).

***New for FY14: Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.*** The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

***Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP;*** if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID ***prior to the application submission deadline (which occurs earlier than the end of the application verification period).***

**Grants.gov application package components:** For the Clinical 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 (10-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

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. Note: For clinical trials, the Project Narrative is NOT the formal clinical trial protocol. Instead, all elements of the proposed clinical trial necessary for peer review must be described as indicated below.***

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, preliminary and/or preclinical data that led to the development of the proposed clinical trial and/or correlative study. Explain why the proposed research question fills an unmet need or is a high-impact research opportunity in ovarian cancer within the continuum of translational research. Clearly support the choice of variables and explain the basis for the study question(s) and/or study hypothesis. Explain how the results of this research effort will be shared with the ovarian cancer research and consumer advocacy communities to maximize sharing and leveraging and to 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 this OCRP award would fund.
- **Research Strategy:** Describe the type of research to be performed (e.g., phase/class, prospective, randomized, controlled, correlative, etc.) and the experimental design, methods, and analyses, including appropriate controls, in sufficient detail.
  - Address potential problem areas and present alternative methods and approaches.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (i.e., convenience, simple random, stratified random). Address potential barriers to accrual and plans for addressing potential delays. Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified random, blinding, age-matched controls, alternating group, or other procedures), if applicable. Include a discussion of risk/benefit considerations. Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide an explanation of how the ethical issues will be addressed.
  - Document the availability and accessibility of the drug/compound, device, human-based samples, or other materials needed.
  - Describe in detail the laboratory evaluations (correlative studies) to be conducted).
- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is

appropriate to meet the objectives of the study. Specify the approximate number of human subjects/samples that will be accrued. If multiple study sites are involved, state the approximate number of subjects to be enrolled at each site and how population differences will be controlled for or taken into account at each site.

- **Study Personnel:** Identify the key members of the study team and describe their roles on the project. If applicable to a proposed clinical trial, a medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.
- **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 of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal 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 whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government 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 in Attachment 2. 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, confirming 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 the PI has the support or resources necessary for the proposed work.
  - **Intellectual Property**
    - **Background and Proprietary Information (if applicable):** All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations

(DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.

- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

The technical abstract is used by all reviewers. Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Describe the study design including appropriate controls.
- Clinical 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 long-term impact. Describe the potential impact of the proposed research on the health and welfare of military Service Members, their Families, and other military beneficiaries.

- **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 how the proposed research is relevant to the vision and mission of the OCRP.
- Describe the impact that the proposed study could, whether short-term or long-

term, have on ovarian cancer.

- Which individuals will it help, and how will it help them?
- What are the potential clinical applications, benefits, and risks (potential long-term outcomes)? If the research is too basic for clinical applicability, describe the short-term outcomes.
- What is the potential impact of the proposed research on the health and welfare of military Service Members, their Families, and other military beneficiaries?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Clinical Translational Leverage Award mechanism, use the SOW format example titled “SOW (Statement of Work) for Clinical Research.” The SOW must be in PDF format prior to attaching.

- **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 has 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. Briefly describe how the outcomes of this research will be shared with the ovarian cancer community to maximize leveraging and remove barriers in future ovarian cancer research or patient care.
- **Attachment 7: IND/IDE Documentation Form (if applicable):** Upload as “IND.IDE.pdf.”

If applicable, complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Previous/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 Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., 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.5., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

#### **D. Verification of Grants.gov Application in eBRAP**

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. *The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*

#### **E. 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 either of these deadlines will result in application rejection.

#### **F. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status 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 applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on (a) technical merit and (b) the relevance to the mission of the DHP and OCRP and to 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 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. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment 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 Process**

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

- **Study Design**
  - How well 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, and methods have been developed and how well they support completion of the aims.
  - To what degree the sample size (human-based samples, data, or human subjects) is appropriate to meet the objectives of the study.
  - To what extent the data will be collected and analyzed in a manner consistent with the study objectives.
  - How well the preliminary data support the proposed research.
  - How well the PI identifies potential problems and addresses alternative approaches.

- *For applications proposing clinical trials:*
  - How well the inclusion, exclusion, and randomization criteria meet the needs of the proposed clinical trial and how well the level of risk to the human subjects is minimized.
  - To what degree the intervention addresses the clinical need(s) described.
  - Whether there is sufficient evidence of an existing IND/IDE (if applicable).
  - Whether there is sufficient evidence of availability and accessibility of the drug/compound, device, and/or materials needed.
- **Recruitment, Accrual, and Feasibility**
  - How well the PI addresses the availability, accessibility, and interest of human subjects for the clinical trial or how well the PI has justified the availability and accessibility of human-based resources for correlative studies.
  - To what extent protocols and methods have been standardized so that resources are judiciously used.
  - How well the recruitment process for human subjects, or the collection process for human-based resources, is designed to meet the needs of the proposed study.
  - How well contingency plans will resolve potential delays (e.g., slow accrual, attrition, collection of samples), if applicable.
- **Impact**
  - How well 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- and long-term impact.
  - How the outcomes of this research will be shared with the ovarian cancer community to maximize leveraging and remove barriers in future ovarian cancer research or patient care.
- **Personnel**
  - Whether the composition of the research team is appropriate.
  - To what extent the research team's background, experience, and expertise are appropriate to execute the proposed work.
  - To what extent the levels of effort by the PI and other key personnel will ensure success of the proposed work.

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

- **Environment**
  - Whether the scientific environment is appropriate for the proposed research.

- To what extent the quality and extent of institutional support are appropriate for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
  - **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 influence the review.
- 2. Programmatic Review:** To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
- a. Ratings and evaluations of the peer reviewers**
  - b. Relevance to the mission of the DHP and FY14 OCRP, as evidenced by the following:**
    - Relative impact on ovarian cancer
    - Program portfolio balance
    - Adherence to the intent of the award mechanism

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **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 email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP 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:

- Submission of an application for which a letter of invitation was not received.
- 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.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

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

- A FY14 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 documentation. A list of the FY14 OCRP IP members can be found at <http://cdmrp.army.mil/ocrp/panels/panels14.shtml>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The PI does not meet the eligibility criteria.

#### **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 USAMRAA 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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

#### **D. Reporting**

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

#### **E. Award Transfers**

Changes in PI and organization are allowed, and will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section M, 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 eBRAP 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: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through 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: 800-518-4726

Email: [support@grants.gov](mailto: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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	IND/IDE Documentation Form (if applicable): Upload as Attachment 7 with file name "IND.IDE.pdf."	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/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 Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete 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.	