

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Ovarian Cancer Research Program

### Clinical Translational Award

**Funding Opportunity Number: W81XWH-15-OCRP-CTA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), May 6, 2015
- **Invitation to Submit an Application:** June, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, August 5, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, August 10, 2015
- **Peer Review:** September 2015
- **Programmatic Review:** December 2015

*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.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2015 (FY15) Ovarian Cancer Research Program (OCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The OCRP was initiated in FY97 to provide support for research of exceptional scientific merit. Appropriations for the OCRP from FY97 through FY14 totaled \$236.45 million (M). The FY15 appropriation is \$20M. The overall goal of the FY15 OCRP is to eliminate ovarian cancer by supporting high-impact research. For additional information concerning the OCRP and its current initiatives, long-term priorities and Integration Panel (IP) members, please refer to the OCRP website at <http://cdmrp.army.mil/ocrp/default>.

The mission of the OCRP is to support patient-centered research to prevent, detect, treat, and cure ovarian cancer. Although not required, investigators are encouraged to address one of the FY15 Areas of Encouragement in their applications:

- Chemoresistance including PARP resistance
- Angiogenesis escape
- Optimizing immunotherapies
- Etiology, epidemiology, and prevention
- Synthetic lethality

### B. Award Information

The intent of the OCRP Clinical Translational Award mechanism is to support translational research addressing high-impact ideas or unmet needs in ovarian cancer. This award supports preclinical and clinical research studies. ***Clinical trials are not supported by this award mechanism.*** Although not intended to fund clinical trials, the Clinical Translational Award can also be used to support research projects related to or associated with ongoing or completed clinical trials supported by other funding sources. Preliminary data are required.

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 Award:

- The proposed research study must be based on sound scientific rationale that is established through logical reasoning, critical review and analysis of the literature, and preliminary data.
- The application must detail how the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer **or** patient care (which may include survivorship issues).
- The application must demonstrate availability and accessibility of the appropriate human subject population or human-based resources. The application will also provide a detailed statistical analysis plan that includes a power analysis reflecting sample size projections that will allow a meaningful outcome.

**Research Involving 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. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

*The CDMRP intends that information, 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 3, 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, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$300,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$300,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- 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.

Refer to the General Application Instructions, Section II.C.5., 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.5. 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
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Shall not be requested for:

- Tuition
- Clinical trial costs

Intramural (DoD), other Federal agency, 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. 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.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. 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 may be executed through a direct fund transfer (e.g., 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. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

***The CDMRP expects to allot approximately \$1.44M of the \$20M FY15 OCRP appropriation to fund approximately three Clinical Translational 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 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.

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/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the

full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

*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.*

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-OCRP-CTA in Grants.gov (<http://www.grants.gov/>).

#### **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. 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**
  - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY15 OCRP 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.

- **Conflicts of Interest (COIs) – Tab 4**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

**Note:** Upload document(s) as individual PDF files 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 research. If the proposed study is related to or associated with an ongoing or completed clinical trial, describe the relationship between the intervention and the question(s) to be studied.
- **Hypothesis:** State the hypothesis to be tested.
- **Study Design:** Describe the design of the research approach for the proposed study. The description should include:
  - The study variables and proposed measurement(s).
  - The research team’s capabilities in conducting the proposed work, 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 study within 6 months of the award date.
- **Clinical Impact:** Explain how the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer **or** patient care (which may include survivorship issues).

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application **must be uploaded as individual documents** 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.
- Key Personnel Biographical Sketches (five-page limit per individual).
- Additional Information (one-page limit): One page for additional information can be used, at the PI's discretion, to provide supporting data or rationale for the pre-application. If no additional information will be submitted, include a page with the statement "No additional information."
- **Submit Pre-Application – Tab 6**
  - 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.
- **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible, is based on sound scientific rationale, and allows the hypothesis to be tested.
- **Impact:** How well the research will provide new paradigms or insights in ovarian cancer **or** patient care (which may include survivorship issues).
- **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 weaknesses) 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. Full Application Submission Content and Forms**

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

*The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.*

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

**Grants.gov application package components:** For the Clinical Translational 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**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **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 may 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.*

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 research 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.
- **Hypothesis:** State the hypothesis to be tested.
- **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 design of the research approach for the proposed study. The description should include:
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls if applicable.
  - Describe the study population, criteria for inclusion/exclusion, and the methods used for recruitment/accrual of human subjects and/or samples (i.e., convenience, simple random, stratified random).
  - Address potential problem areas and present alternative methods and approaches.
- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study aims. Include a complete power analysis to demonstrate that the sample size is appropriate to test the hypothesis. Specify the approximate number of human subjects or samples that will be used. All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research. [Nature 2012 490:187-191](#).
- **Study Personnel:** Identify the key members of the study team and describe their roles on the project.
- **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 will result in the removal of those items or may result in 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 of each 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 support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration: 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: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. 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 3, 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.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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.

Technical abstracts should be written using the outline below:

- Background: Present the ideas and reasoning behind the proposed work.
- Hypothesis: State the hypothesis to be tested. Provide evidence or rationale that supports the 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. Detail how the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer **or** patient care (which may include survivorship issues). 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.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay 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 lay abstract for appropriate description of the project’s key aspects.

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

Do not duplicate the technical abstract. Lay abstracts should be written using the outline below:

- Clearly describe, in a manner readily understood by lay persons, the rationale 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 how the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer **or** patient care (which may include survivorship issues).
  - 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.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Clinical Translational 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. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **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 high impact on ovarian cancer research. Describe the expected outcomes, and anticipated benefits. Explain how the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer or patient care (which may include survivorship issues).
  - **Attachment 7: Additional Information (one-page limit): Upload as “AddInfo.pdf.”** One page for additional information that the PI can use, at his/her discretion, to provide supporting data or rationale or justification for the proposed work. If no additional information will be supplied, leave Attachment 7 blank.
  - **Attachment 8: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded within a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
- PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (five-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.5., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **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 DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration 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 DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, 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>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure 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 preliminary data support the proposed research.
  - How well the hypotheses, experimental design, and methods have been developed and how well they support completion of the aims.
  - To what degree the sample size is appropriate to test the hypothesis and how the accessibility and availability of human subjects, samples, or data is justified.
  - To what extent the data will be collected and analyzed in a manner consistent with the study aims.
  - How well the PI identifies potential problems and addresses alternative approaches.
- **Impact**
  - How well the outcomes of the proposed research will provide new paradigms or insights in ovarian cancer **or** patient care (including survivorship issues).
  - How well the proposed research question fills an unmet need in or has high impact on ovarian cancer.
- **Personnel**
  - 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 and select the application(s) that, individually or collectively, will best achieve the program objectives, 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 FY15 OCRP, as evidenced by the following:**

- Relative impact on ovarian cancer
- Program portfolio composition and 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.
- The proposed research is, or requests funding for, a clinical trial.
- The PI does not meet the eligibility criteria.
- 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.

### **C. Withdrawal**

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

- A FY15 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 FY15 OCRP IP members can be found at <http://cdmrp.army.mil/ocrp/panels/panels15>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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 proposed research has overlap with a current or previously funded research project to the PI and organization.

#### **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, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

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

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

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

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

#### **D. Reporting**

Refer to the General Application Instructions, Appendix 3, Section I, 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 3, 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 Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Additional Information: Upload as Attachment 7 with file name "AddInfo.pdf."	
	8	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 8 with file name "MFBudget.pdf," if applicable.	
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.	