

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Ovarian Cancer Research Program

### Ovarian Cancer Academy Award – Early-Career Investigator

Funding Opportunity Number: W81XWH-14-OCRP-OCA

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 FY14:*** *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 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). 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 high-impact innovative research. The OCRP's long-term priorities are as follows:

- 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;
- Understand tumor response to therapy including tumor survival, dormancy, cell death, clonal evolution, and tumor heterogeneity; and
- Enhance the pool of ovarian cancer scientists.

### B. Award Information

The OCRP Ovarian Cancer Academy, which was initially created in FY09, is intended to be a unique, interactive virtual academy providing intensive mentoring, national networking, and a peer group for junior faculty. The overarching goal of the Ovarian Cancer Academy is to develop successful, highly productive ovarian cancer researchers in a collaborative research training environment. The Ovarian Cancer Academy is a virtual career development and research training platform that currently consists of nine Early-Career Investigator/Designated Mentor pairs from different institutions and one Academy Dean; two additional Early-Career Investigator/Designated Mentor pairs are pending awards. Information about the Academy is available in the FY12 and FY13 Ovarian Cancer Program Booklets at <http://cdmrp.army.mil/ocrp/pbks/pbks>. The Academy Dean serves as a resource for the Early-Career Investigators and Designated Mentors, assessing the progress of the Early-Career Investigators, and facilitating communication and collaboration among all of the Early-Career Investigators and Mentors.

This FY14 Program Announcement/Funding Opportunity is soliciting additional Early-Career Investigators to join the existing Academy. Applications to this award mechanism must be submitted by the Early-Career Investigator as the Principal Investigator (PI).

Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to be derived from the ovarian cancer research field. ***Clinical trials are not allowed under this mechanism.***

The Early-Career Investigator, who will be the PI of the application, must be in the early stage of his/her career. This award provides the Early-Career Investigator with funding, networking opportunities, and research experience necessary to develop and sustain a successful, independent career at the forefront of ovarian cancer research. This award also provides support and protected time for the Early-Career Investigator for 5 years of intensive research under the guidance of a Designated Mentor experienced in ovarian cancer research. Although the Ovarian Cancer Academy will serve as a conduit to share knowledge and research experience among all academy members, the Early-Career Investigator and his/her Designated Mentor will be responsible for developing the Early-Career Investigator's career development plans and for designing and executing the proposed research. The Early-Career Investigator must clearly articulate his/her commitment to a career as an ovarian cancer researcher.

The Designated Mentor must have a strong record of mentoring and training early-career investigators. In addition to being a Designated Mentor to an Early-Career Investigator at his/her institution, the Designated Mentor must agree to serve as a secondary Mentor to another Ovarian Cancer Academy Early-Career Investigator who may or may not be at the Designated Mentor's institution.

The Early-Career Investigator and Designated Mentor are required to attend a Department of Defense (DoD) OCRP biennial multi-day workshop, and in alternate years, a DoD OCRP 1-day workshop.

**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**

- **Early-Career Investigator**

- Must be within the first 3 years of his/her first faculty position (or equivalent) at the time of submission. The first faculty position (or equivalent) may be either tenure-track or non-tenure-track.

- May be research or physician-scientist.
- Must have an institutional commitment of at least 50% protected time. Must commit no less than 25% effort to this award.
- Must receive an institutional support package of at least \$50,000 per year (e.g., supplies, staff, salary, and start-up package) to use in support of the career development of the Early Career Investigator.
- **Designated Mentor**
  - Must be at the same institution as the Early-Career Investigator.
  - Must be an independent, established ovarian cancer researcher.
  - Must have ovarian cancer research funding (past and present).
  - Must have a record of ovarian cancer publications in peer reviewed journals.
  - Must demonstrate a commitment (at least 10% effort for mentoring and participating in off-site Academy activities) to develop and sustain the Early-Career Investigator's independent career in ovarian cancer research.
    - Mentoring responsibilities include mentoring the designated Early-Career Investigator and an additional Early-Career Investigator within the Academy.
    - Off-site Academy activities include annual in-person workshops and periodic web-based meetings.
- Cost sharing/matching is not an eligibility requirement.
- The institution must commit to protecting at least 50% of the Early-Career Investigator's time and must provide institutional support of at least \$50,000 per year (e.g., supplies, staff, salary, and start-up package) in support of the career development of the Early Career Investigator.
- 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 **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$725,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

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:

Must be requested for:

- Travel costs for the Early-Career Investigator and Designated Mentor to an annual DoD OCRP 1-day workshop with the Academy Dean and other Academy members
- Travel costs for the Early-Career Investigator and Designated Mentor to a biennial DoD OCRP multi-day workshop with the OCRP staff, Academy Dean, and other Academy members

May be requested for (not all-inclusive):

- Salary (Early-Career Investigator, Designated Mentor, research staff)
  - Maximum allowable funding for the Designated Mentor is \$30,000 per year in direct costs
- Research Supplies
- Research-related subject costs
- Equipment
- Tuition for training and/or other educational opportunities for the Early-Career Investigator
- Consultation with scientific and/or technical experts (e.g., statistician, editors)
- Travel between collaborating organizations
- Cost associated with participating in the virtual academy (e.g., hardware and/or software for the audio- or video-teleconferencing or web-based communications)
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required meetings described above

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 \$2.32M of the \$20M FY14 appropriation to fund approximately two Ovarian Cancer Academy – Early Career Investigator 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-OCA.

#### **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, Designated Mentors, and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. A change in PI, designated Mentor 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 change is 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:

Describe the Early-Career Investigator's (PI on this award) career goals in ovarian cancer research. Briefly describe the career development plan and how the Designated Mentor will assist the Early-Career Investigator in not only developing, but also sustaining, his/her career as an independent ovarian cancer researcher. Briefly describe the proposed research idea in ovarian cancer that will be supported by this award, as well as the ability of the Early-Career Investigator to conduct the research or the relevant training that will be obtained to accomplish the project. Describe the Early-Career Investigator's commitment to participating in the Ovarian Cancer Academy. Summarize how the proposed research and career development experience will promote an independent, sustainable career in ovarian cancer research.

**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.
- Early-Career Investigator Biographical Sketch (four-page limit). The biographical sketch should support the personal statement.
- Designated Mentor Biographical Sketch (four-page limit).
- **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:

- The Early-Career Investigator's (PI) career goals in ovarian cancer research
- The proposed research and career development plans
- How the Designated Mentor will assist the Early-Career Investigator

- The Early-Career Investigator’s commitment to participating in the Ovarian Cancer Academy
- 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 Ovarian Cancer Academy – Early Career Investigator 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.

Describe the proposed project in detail using the outline below.

- **Early-Career Investigator's Career Goals** (one-page limit recommended): Discuss the Early-Career Investigator's record of accomplishments that demonstrate his/her potential for becoming an independent investigator in ovarian cancer research. Describe the Early-Career Investigator's career goals in ovarian cancer research and how the proposed research and career development experience will promote an independent, sustainable career. Discuss the Early-Career Investigator's career plans to include continuing as an ovarian cancer researcher after the completion of this award.
- **Career Development and Sustainment Plan** (one-page limit recommended): Describe the career development plan, which may include training, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Explain how this career development plan will allow the Early-Career Investigator to obtain independent ovarian cancer research funding and publish in peer-reviewed journals, thereby sustaining an independent career at the forefront of ovarian cancer research. Discuss how the Designated Mentor will assist the Early-Career Investigator in not only developing, but also sustaining, his/her career as an independent ovarian cancer researcher. Explain how the career development plan is supported by the environment; this should include a description of ongoing ovarian cancer research and available resources at the institution. Outline how the Early-Career Investigator and Designated Mentor will evaluate the Early-Career Investigator's progress of achieving and sustaining a productive career in ovarian cancer research.
- **Research Project** (six-page limit recommended): Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for analysis. Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to come from the ovarian cancer research field. Address potential problem areas and present alternative methods and approaches. If the proposed project uses human subjects or human biological samples, include a detailed plan for the recruitment of subjects or the acquisition of samples. The research description should also describe the ability of the Early-Career Investigator to conduct the research or the relevant training that will be obtained to accomplish the project. This award may not be used to conduct clinical trials.
- **Integration of Career Development and Research** (one-page limit recommended): Describe how the career development plan and research project are integrated and how they will contribute to preparing the Early-Career Investigator for an independent, sustainable career in ovarian cancer research.
- **Commitment to the Ovarian Cancer Academy** (one-page limit recommended): Describe the Early-Career Investigator's commitment to participating in the Ovarian Cancer Academy, to include networking and

collaborating with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean.

- **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.
    - For the Early-Career Investigator application, the institution must demonstrate a commitment to the Early-Career Investigator through at least 50% protected time with no less than 25% effort committed to this award. Describe in detail, the institutional support of \$50,000 per year (e.g., supplies, staff, salary, start-up package) for 5 years that the institution will provide to the career development of the Early-Career Investigator.
  - 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 peer and programmatic reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects.

- Career Development Plan
  - Summarize how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator’s independent career at the forefront of ovarian cancer research.
  - Describe how the proposed research project will train the PI to make valuable contributions to ovarian cancer.
- Research Plan
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide supporting evidence or rationale.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design, including appropriate controls.
- Impact: Describe how the proposed research will make important short-term or long-term contributions toward the goal of eliminating ovarian cancer. 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.”
  - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the PI’s career goals in ovarian cancer research.

- How does the research and training plan support the PI in attaining these goals?
- Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely short-term or long-term contributions of this study to advancing the field of ovarian cancer research?
- 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 Ovarian Cancer Academy Award – Early-Career Investigator mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Explain how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator’s independent career at the forefront of ovarian cancer research. Describe how the proposed research will make important short-term or long-term contributions toward the goal of eliminating ovarian cancer.
- **Attachment 7: Designated Mentor’s Letter for the Early-Career Investigator application (three-page limit):** Upload as “MentorLetter.pdf.”
  - The Designated Mentor’s letter should describe the Early-Career Investigator’s background and potential to become an independent ovarian cancer researcher. Explain how this award will enhance the Early-Career Investigator’s capabilities to sustain a career in ovarian cancer research.
  - Describe the Designated Mentor’s background and experience in ovarian cancer research, success in acquiring funding in ovarian cancer research, and record of mentoring and training young investigators. Specify the commitment of the Designated Mentor (at least 10% effort) and his/her staff to the Early-Career Investigator’s professional development and career sustainment. Describe the specific resources that will facilitate success for the Early-Career Investigator.

- Describe the Designated Mentor’s commitment to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean. Describe the Designated Mentor’s commitment and time to serve as a secondary mentor to another Early-Career Investigator in the Ovarian Cancer Academy.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
- Early-Career Investigator Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
  - Early-Career Investigator 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.”
    - Include the Designated Mentor’s biographical sketch.
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Include the Designated Mentor’s previous/current/pending support.
- 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 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, 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>.

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 listed in decreasing order of importance:

- **Early-Career Investigator**

- To what extent the Early-Career Investigator's record of accomplishments demonstrates his/her potential for becoming an independent investigator in ovarian cancer research.
- To what degree the Early-Career Investigator's career goals are consistent with a commitment to pursuing and sustaining a career as an ovarian cancer researcher.
- Whether the Early-Career Investigator meets the appropriate eligibility requirements.
- Whether the level of effort of the Early-Career Investigator meets the requirements (at least 50% protected time and no less than 25% effort committed to this award) and is appropriate for successful conduct of the proposed work.
- How well the Designated Mentor's letter supports the Early-Career Investigator's potential for a productive, sustainable, and independent career in ovarian cancer research.
- To what extent the Early-Career Investigator is committed to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Dean.

- **Career Development and Sustainment Plan**

- How well the Early-Career Investigator has outlined an individualized Career Development and Sustainment Plan that is consistent with the Ovarian Cancer Academy and the Early-Career Investigator's research goals.
- How well the Career Development and Sustainment Plan will contribute to the overall professional development of the Early-Career Investigator and prepare the Early-Career Investigator for an independent, productive career in ovarian cancer research.
- Thoroughness of the plans for monitoring and evaluating the Early-Career Investigator's progress in becoming an independent investigator.

- **Designated Mentor**

- To what extent the Designated Mentor's background, research experience, and funding history will be supportive of the Early-Career Investigator's career development needs and transition to independence.

- To what degree the Designated Mentor is an independent, established ovarian cancer researcher with ovarian cancer research funding (past and present) and a record of ovarian cancer publications in peer reviewed journals.
- How well the Designated Mentor's track record in preparing investigators for careers in ovarian cancer research indicates the potential for successful mentorship and development of the Early-Career Investigator as an independent investigator.
- How the quality of the Career Development and Sustainment Plan and research project suggests that the Designated Mentor has provided appropriate guidance.
- **Research Strategy and Feasibility**
  - To what extent the scientific rationale supports the research project and its feasibility as demonstrated by a review and analysis of the literature and relevant preliminary data (preliminary data do not need to come from the ovarian cancer research field).
  - How well the hypotheses or objectives, experimental design, methods, and analyses are developed and support completion of the aims.
  - How well the Early-Career Investigator acknowledges potential problems and addresses alternative approaches.
- **Impact**
  - To what extent the proposed research and Career Development and Sustainment Plan will facilitate and sustain the Early-Career Investigator's independent career at the forefront of ovarian cancer research.
  - To what extent the proposed research makes an important short-term or long-term contribution to advancing the field of ovarian cancer research.
- **Resources**
  - To what extent the proposed research project and career development of the Early-Career Investigator is supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.
  - How well the commitments from the institution (of at least 50% protected time and institutional support of \$50,000 per year, e.g., supplies, staff, salary, start-up package, for 5 years) supports the Early-Career Investigators.

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

- **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.
  - **Intellectual Property and Material**
    - If applicable, to what degree the intellectual and material property plan is appropriate.
- 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
    - Program portfolio balance and composition
    - Programmatic relevance
    - 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>.
- 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 proposed research is, or requests funding for, a clinical trial.
- The Early-Career Investigator does not meet the eligibility criteria.
- The Designated Mentor 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 are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. Maintaining the Designated Mentor upon institutional transfer will be evaluated on a case-by-case basis at the discretion of the Grants Officer, but must be resolved prior to award transfer. 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."	
	Designated Mentor's Letter: Upload as Attachment 7 with file name "MentorLetter.pdf."	
Research & Related Senior/Key Person Profile (Expanded)	Attach Early-Career Investigator Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach Early-Career Investigator 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.	