

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Ovarian Cancer Research Program

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

Funding Opportunity Number: W81XWH-15-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), May 13, 2015
- **Invitation to Submit an Application:** June, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, August 12, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, August 17, 2015
- **Peer Review:** October 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) 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. The mission of the OCRP is to support patient-centered research to prevent, detect, treat, and cure ovarian cancer. 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>.

### 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 11 Early-Career Investigator/Designated Mentor pairs from different institutions and 1 Academy Dean; 3 additional Early-Career Investigator/Designated Mentor pairs and the new Academy Leadership (Dean and Assistant Dean) are pending awards. In addition, three to four Early-Career Investigators are expected to graduate from the Academy in the summer of 2015, but may remain associated with the Academy via the FY14 Ovarian Cancer Academy Collaborative Award. Information about the Academy is available in the FY12, FY13, and FY14 Ovarian Cancer Program Booklets at <http://cdmrp.army.mil/ocrp/pbks/pbks>. The Academy Leadership serves as a resource for the Early-Career Investigators and Mentors, assessing the progress of the Early-Career Investigators, and facilitating communication and collaboration among all of the Early-Career Investigators and Mentors, as well as with national research and advocacy communities.

This FY15 Program Announcement/Funding Opportunity is soliciting additional Early-Career Investigators to join the existing Academy. This award mechanism enables the Early-Career Investigator (the Principal Investigator [PI] on the application) to pursue an ovarian cancer project that may be basic, translational, and/or clinical research, under the guidance of a Designated Mentor. 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.***

***NEW for FY15: The OCRP encourages Early-Career Investigators whose ability to commit to conducting ovarian cancer research is limited by either minimal or a lack of resources such as a qualified Designated Mentor at his/her institution, access to ovarian cancer research tools, opportunities for establishing collaborations, etc.*** Also, the Designated Mentor does not have to be at the Early-Career Investigator's institution.

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, the Designated Mentor must agree to serve as a secondary Mentor to another Ovarian Cancer Academy – Early-Career Investigator.

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.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All 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.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Refer to General Application Instructions, Appendix 5, 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. Eligibility Information.***

## C. Eligibility Information

- **Early-Career Investigator**

- Eligibility Information
- 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 a research or physician-scientist.
- Must not have a concurrent Career Development-like award at the time of this award.
- Must have an institutional commitment of approximately 50% protected time for ovarian cancer research.
- Must commit no less than 25% effort to this award for the first 2 years.

- **Designated Mentor**

- Should be at the same institution as the Early-Career Investigator; if not at the same institution, another Mentor (Other Mentor, who does not have to meet the Designated Mentor eligibility requirements) at the Early-Career Investigator's institution must also be included in the application submission.
- 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.

- **Other Mentor (if applicable)**

- Must be an independent researcher with an expertise related to the proposed research.
- Must have research funding (past and present)

- 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 **5** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$725,000**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$725,000** 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.

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 must be requested for:

- Travel costs for the Early-Career Investigator and Designated Mentor (and Other Mentor, if applicable) to a DoD OCRP 1-day workshop with the Academy Leadership and other Academy members every other year.
- Travel costs for the Early-Career Investigator and Designated Mentor (and Other Mentor, if applicable) to a biennial DoD OCRP multi-day workshop with the OCRP staff, Academy Leadership, and other Academy members.

May be requested for (not all-inclusive):

- Salary (Early-Career Investigator, Designated Mentor, Other Mentor, if applicable, research staff)
  - Maximum allowable funding for the Designated Mentor is \$30,000 per year in direct costs
  - If applicable, funding for the Other Mentor must be justified.
- 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 to attend scientific/technical meetings

Shall not be requested for:

- Tuition for graduate students

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 \$2.32M of the \$20M FY15 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 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-OCA 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**

**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.
- Describe the career development plan and how the Designated Mentor (and Other Mentor, if applicable) will assist the Early-Career Investigator in developing and sustaining his/her career as an independent ovarian cancer researcher.
- If applicable, describe how research in ovarian cancer is/has been limited by either minimal or a lack of resources and how this will be resolved. Briefly describe the proposed ovarian cancer research idea 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 motivation and 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 one file*, 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 (five-page limit).
- Early-Career Investigator Previous/Current/Pending Support (no page limit).
- Designated Mentor Biographical Sketch (five-page limit).
- Designated Mentor Previous/Current/Pending Support (no page limit).
- Other Mentor Biographical Sketch, if applicable (five-page limit).
- **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:

- The Early-Career Investigator’s (PI’s) career goals in ovarian cancer research
- The proposed research and career development plans
- How the Designated Mentor, and Other Mentor, if applicable, will assist the Early-Career Investigator
- The Early-Career Investigator’s motivation and 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. 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 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**

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.

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 individualized 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 and Other Mentor, if applicable, 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 resources available to the ECI at his/her institution and, if different, at the Designated Mentor's institution. Outline how the Early-Career Investigator and Designated Mentor (and Other Mentor, if applicable), 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): Concisely explain the project's specific aims to be funded by this application. 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 individualized 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 motivation and commitment to participating in the Ovarian Cancer Academy, to include

networking and collaborating with the other Early-Career Investigator/ Designated Mentor pairs (if applicable, Other Mentor) and the Academy Leadership.

- **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/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 for ovarian cancer research
      - No less than 25% effort committed to this award for the first 2 years
    - Describe what, if any, support (e.g., supplies, staff, salary, start-up package) the institution plans to provide in support of the Early-Career Investigator’s career development during the 5-year period of performance of this award..
  - 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.

- 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.
- 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:

- 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: State 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.”** 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 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:

- Describe the hypothesis 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 our knowledge of ovarian cancer?
  - 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 Ovarian Cancer Academy – Early-Career Investigator Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” 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.”**  
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 motivation and commitment to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Leadership. Describe the Designated Mentor’s commitment and time to serve as a secondary mentor to another Early-Career Investigator in the Ovarian Cancer Academy.
- **Attachment 8: If Applicable, Other Mentor’s Letter for the Early-Career Investigator application (two-page limit): Upload as “OtherMentor.pdf.”**
  - The Other 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 Other Mentor’s background and experience in research, success in acquiring funding, and record of mentoring and training young investigators. Describe the specific resources that will facilitate success for the Early-Career Investigator.

- Describe the Other Mentor’s motivation and commitment to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Leadership.
- **Attachment 9: 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.”
    - Include the Designated Mentor’s biographical sketch.
    - Include the Other Mentor’s biographical sketch, if applicable.
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Include the Designated Mentor’s previous/current/pending support.
    - Include the Other Mentor’s previous/current/pending support, if applicable.
- 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 highestscoring 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 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](#).
    - How well the Designated Mentor's letter (and if applicable, Other 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 motivated and committed to participating in the Ovarian Cancer Academy with the other Early-Career Investigator/Designated Mentor pairs and the Academy Leadership.
  - **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, experimental design, methods, and analyses are developed and support completion of the aims.
    - How well the potential problems are identified and alternative approaches are addressed.
  - **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 individualized 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 (and if applicable, Other Mentor)**
  - To what extent the Designated Mentor's (and if applicable, Other 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 individualized Career Development and Sustainment Plan and research project suggests that the Designated Mentor (and if applicable, Other Mentor) has provided appropriate guidance.
- **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 toward the goal of eliminating ovarian cancer.
- **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 commitment from the institution (of at least 50% protected time) supports the career development of the Early-Career Investigator.
  - If applicable, how well the institutional support (e.g., supplies, staff, salary, start-up package) committed by the institution will support the career development of the Early-Career Investigator.

- If applicable, how well the application will overcome the lack of or minimal resources that limit the PI's ability to commit to conducting ovarian cancer research.

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.

- **Environment**

- If applicable, to what degree the intellectual and material property plan is appropriate.

**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
- 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.
- 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.
- 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://cdmnp.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 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.

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	Designated Mentor's Letter: Upload as Attachment 7 with file name "MentorLetter.pdf."	
	8	Other Mentor's Letter: Upload as Attachment 8 with file name "OtherMentor.pdf," if applicable.	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 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.	