# Program Announcement

for the

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

# Ovarian Cancer Research Program

## Pilot Award

**Funding Opportunity Number:  W81XWH-14-OCRP-PA**

**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 22, 2014
- **Invitation to Submit an Application:**  July 2014
- **Application Submission Deadline:**  11:59 p.m. ET, August 20, 2014
- **End of Application Verification Period:**  5:00 p.m. ET, August 25, 2014
- **Peer Review:**  October 2014
- **Programmatic Review:**  December 2014

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

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

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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).  The OCRP was initiated in FY97 to provide support for research of exceptional scientific merit. Appropriations for the OCRP from FY97 through FY13 totaled $216.45 million (M).  The FY14 appropriation is $20M.  The overall goal of the FY14 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.  The OCRP's long-term priorities are:

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

## B.   Award Information

The OCRP Pilot Award supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will drive the field of ovarian cancer research forward.  The proposed research must demonstrate a clear focus on ovarian cancer (e.g., using tissues, cell lines, datasets, or appropriate animal models, etc.).  The proposed research should include a testable hypothesis based on strong scientific rationale and serve as a catalyst to expand or modify current thinking about and/or approaches in ovarian cancer research.  ***Preliminary data are not required, but are allowed.***  The strength of the application should be based on sound scientific rationale and logical reasoning.  ***Clinical trials will not be supported by this award mechanism.***

**OCRP Definition of Innovation (*UPDATED for FY14*):**  Innovative ideas for the OCRP are those that, if proven correct, will provide new paradigms, insights, technologies, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.

Research that represents an incremental advancement on previously published work is not considered innovative.  The following list, ***although not all-inclusive,*** provides examples of research that is ***not innovative*** and will not be considered for funding under this mechanism:

- Exploring a previously tested hypothesis in a different cell line or in a new population
- Using a published series of in vitro assays to further characterize a model system

- Incorporating known biomarkers into in vivo or clinical models of ovarian cancer
- Investigating the next logical step or continuation of a previous research project
- Proposing work that is an incremental advancement of published data

**Optional Nested Teal Postdoctoral Scholar:**  A nested Teal Postdoctoral Scholar is being offered as an optional feature of the Pilot Award to foster the next generation of ovarian cancer investigators through mentored research training.  Only one postdoctoral fellow (candidate must be named) can be included as a Teal Postdoctoral Scholar within a given application.  The named postdoctoral scholar must remain in said position while supported by this award.  Applications that contain a nested Teal Postdoctoral Scholar will qualify for a higher level of funding as described under Section I.D., Funding below.  Either the Principal Investigator (PI) or a collaborator on the Pilot Award can be designated as the mentor for the proposed optional, nested Teal Postdoctoral Scholar.

**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**

- Investigators at the postdoctoral level and above (and equivalent) from academia, research institutions, industry, government agencies, and private foundations are eligible to submit applications.  Investigators should have dedicated laboratory space but are not required to lead their own laboratory.

- For applications with an *optional nested Teal Postdoctoral Scholar:*  A nested Teal Postdoctoral Scholar is defined as a postdoctoral fellow who has spent no more than 3 years total in all postdoctoral positions or equivalent at the time of application submission.

- Cost sharing/matching is not an eligibility requirement.

- Eligible investigators must apply through an organization.  Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.  Both intramural (i.e., DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

**D.    Funding**

- The maximum period of performance is **2** years.

- The maximum allowable direct costs for the entire period of performance are **$225,000** plus indirect costs.

- ***Optional Teal Postdoctoral Scholar:***  If requesting an optional nested Teal Postdoctoral Scholar, an additional $75,000 is allowed to support the postdoctoral scholar, for a maximum allowable direct cost for the entire period of performance of **$300,000** 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.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

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

For this award mechanism, direct costs:

May be requested for (not all-inclusive):
- Salary

- Research Supplies

- Equipment

- Research-related subject costs

- Travel between collaborating organizations

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

- Additional travel costs of up to $1,800 per year for a nested Teal Postdoctoral Scholar to attend ovarian-cancer specific meetings (if applicable)

Shall not be requested for:

- Tuition

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

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

*The CDMRP expects to allot approximately $5.64M of the $20M FY14 OCRP appropriation to fund approximately 15 Pilot 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 <u>strongly</u> 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/](http://www.grants.gov/)) basic search using the Funding Opportunity Number: W81XWH-14-OCRP-PA.

## B.    Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP ([https://eBRAP.org/](https://eBRAP.org/)).  Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

***Pre-applications will be screened based on the merits of the proposed research.  Therefore, reviewers will be blinded to the identity of the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, and their organization(s).*** Due to the blinded nature of the review process***, identifying or making references to the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, or their organization(s) within the Preproposal Narrative is prohibited and will result in administrative rejection of the pre-application*** and preclude invitation to submit a full application.  In addition, the use of "I," "we," "our," "this organization," or similar wording in phrases that refer to the PI, collaborators, or their organization(s) through the references listed will also result in administrative rejection of the pre-application and preclude invitation to submit a full application.

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 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 (two-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:

  - **Research Idea:**  State the ideas and reasoning on which the proposed work is based and how the application addresses a central problem in ovarian cancer.

  - **Innovation:**  Describe how the research is innovative and consistent with the OCRP's definition of innovation.

  - **Impact:**  Describe how the proposed research will impact a critical problem or question in ovarian cancer research or patient care in the short or long term.

  **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.

- **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:

  ○ **Blinded Content:**  *Identifying or making references to the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, or their organizations will result in administrative rejection of the pre-application.*

  ○ **Research Idea:**  How well the proposed work addresses a central problem in ovarian cancer.

  ○ **Innovation:**  How the research represents new paradigms, insights, technologies, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.  To what degree the proposed research is more than a continuation of a previous research project, or more than an incremental advance to published data.

  ○ **Impact:**  To what degree the proposed study will impact a critical problem or question in ovarian cancer research or patient care in the short or long term.

- **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 Pilot 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 (six-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.

      *Reviewers will <u>NOT</u> be blinded to the identity of the PI, nested Teal Postdoctoral Scholar (if applicable), collaborators, and their institutions during the peer and programmatic reviews.*

      Describe the proposed project in detail using the outline below.  The Project Narrative should demonstrate logical reasoning and a sound scientific rationale that is established through a critical review and analysis of the literature.  In addition, the Project Narrative should include a description of how the proposed research is innovative as well as its potential impact on ovarian cancer.

      ○ **Background:**  Present the ideas and reasoning behind the proposed research, to include relevant literature citations.  *Preliminary data are not required, but are allowed.*

      ○ **Hypothesis or Objective:**  State the hypothesis to be tested or the objective to be attained.

      ○ **Specific Aims:**  Concisely explain the project's specific aims to be supported by this application.  If this research project is part of a larger study, present only tasks that this OCRP award would fund.

      ○ **Research Strategy:**  Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail.  Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable.  Address potential problem areas and present alternative methods and approaches.  If animals are to be used, explain why the animal model(s) being used can address the scientific objectives.  If human

subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. If appropriate for the proposed research, provide a statistical plan and sample size estimate.

- **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. 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.***

  ○ 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.

  ○ Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy of each manuscript must be included in Attachment 2. Extra items will not be reviewed.

  ○ Letters of Organizational Support (no page limit per letter): 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. **If the PI does not have his/her own laboratory, this letter should confirm that support is available for the proposed project.**

  ○ Letters of Collaboration (if applicable) (no page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

  ○ Intellectual Property

    – Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.

- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  ○ Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

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

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

  ○ Background: Present the ideas and reasoning behind the proposed work.

  ○ Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

  ○ Specific Aims: State the specific aims of the study.

  ○ Study Design: Describe the study design including appropriate controls.

  ○ Innovation: Summarize how the proposed research is innovative and, if proven correct, how it will provide new paradigms, insights, technologies, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.

  ○ Impact: Describe how the proposed research is relevant to vision and mission of the OCRP. Outline the potential short-term or long-term impact of the proposed research on 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."

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

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

  ○ Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.

  ○ Describe the central problem in ovarian cancer addressed in the proposed research.

  ○ Describe how the proposed research is relevant to vision and mission of the OCRP.

- ○ Describe the impact that the proposed study could, whether short-term or long-term, have on ovarian cancer.

    - Which individuals will it help, and how will it help them?

    - What are the potential clinical applications, benefits, and risks (potential long-term outcomes)?  If the research is too basic for clinical applicability, describe the short-term outcomes.

    - What is the potential impact of the proposed research on the health and welfare of military Service Members, their Families, and other military beneficiaries?

- **Attachment 5:  Statement of Work (SOW) (two-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 Pilot Award 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:  Innovation Statement (one-page limit):**  Upload as "Innovation.pdf."  Summarize how the proposed research is innovative according to the OCRP definition of innovation.  Investigating the next logical step or incremental advance on published data is not considered innovative.

- **Attachment 7:  Impact Statement (one-page limit):**  Upload as "Impact.pdf."  Describe a central problem in ovarian cancer addressed in the proposed research.  Explain why the proposed research project is important and how the proposed research is relevant to vision and mission of the OCRP.  Outline the potential short-term or long-term impact of the proposed research on ovarian cancer.

- **Attachment 8:  Optional Nested Teal Postdoctoral Scholar Statement (if applicable) (two-page limit)**:  Upload as "ScholarStatement.pdf."  The Teal Postdoctoral Scholar Statement must be written by the candidate and should articulate the Scholar's career goals, an individualized, ovarian-cancer focused training plan, and how the proposed research training will promote a career as an independent, innovative ovarian cancer researcher.  Describe qualifications and achievements that make the postdoctoral fellow the ideal candidate for the Teal Postdoctoral Scholar.  The Teal Postdoctoral Scholar's commitment to a career in ovarian cancer research is critical and must be described.

- **Attachment 9:  Letter of Support for the Teal Postdoctoral Scholar (if applicable) (no page limit):**  Upload "ScholarSupport.pdf."  If a Teal Postdoctoral Scholar is proposed, a letter of support from the mentor should describe not only the qualifications and achievements that make the postdoctoral fellow an ideal candidate, but should also emphasize the commitment to a career as an independent, innovative ovarian cancer researcher.  The letter should include the statement that the candidate meets eligibility requirements.  The letter should outline the mentor's commitment to

the mentorship of the Teal Postdoctoral Scholar, including details of his/her proposed interactions with the Teal Postdoctoral Scholar.

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.***

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
     ○ Teal Postdoctoral Scholar Biographical Sketch (if applicable).
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
     ○ Teal Postdoctoral Scholar Previous/Current/Pending Support (if applicable).

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."
     ○ ***Optional Nested Teal Postdoctoral Scholar:*** Outline how the additional $75,000 will be used to support the Teal Postdoctoral Scholar.

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.

## E.    Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity.  Pre-application and application submissions are required.  Failure to meet either of these deadlines will result in application rejection.

## F.    Other Submission Requirements

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

All applications must be submitted through Grants.gov.  Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov.  The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal.  Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

## III.   APPLICATION REVIEW INFORMATION

## A.    Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process.  The first tier is peer review of applications against established criteria for determining technical merit.  The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on (a) technical merit and (b) the relevance to the mission of the DHP and OCRP and to the specific intent of the award mechanism.  The highest-scoring applications from the first tier of review are not automatically recommended for funding.  Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process.  Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel.  Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions.  In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process.  Violations of these prohibitions will result in the administrative withdrawal of the organization's application.  Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards.  Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

**B. Application Review Process**

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

- **Innovation**
    ○ To what extent the proposed research will provide new paradigms, insights, technologies, or applications that have the potential to prevent ovarian cancer or improve the treatment of individuals with this disease.
    ○ To what extent the proposed research represents more than an incremental advance of published data or more than the next logical step in a research project.

- **Research Strategy and Feasibility**
    ○ To what extent the scientific rationale supports the hypothesis and feasibility of this pilot project, as demonstrated by a review and analysis of the literature.
    ○ How well the hypotheses or objectives, experimental design, methods, and analyses (and if applicable, the statistical plan, rationale for the statistical methodology, and power analysis) have been developed and how well they support completion of the aims.
    ○ How well the PI identifies potential problems and addresses alternative approaches.
    ○ How preliminary data, if included, support the proposed research.
    ○ If the study proposes using animals, how well the proposed model is appropriate to accomplish the proposed work.
    ○ If human subjects or human anatomical samples will be used, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.

- **Impact**
    ○ To what extent the anticipated short-term outcome(s) of the proposed research project will impact ovarian cancer research and/or patient care.
    ○ To what extent the anticipated long-term gains from the proposed research will contribute to the goal of eliminating cancer.

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

- **Personnel**
    ○ To what extent the PI's background, experience, and expertise are appropriate to execute the proposed work.
    ○ To what extent the key personnel(s) background, experience, and expertise are appropriate to execute the proposed work.

- How, if applicable, the nested Teal Postdoctoral Scholar's career goals, future plans, qualifications, achievements, proposed research training, and demonstrated commitment will promote a career in ovarian cancer research.
- To what degree the levels of effort by the PI and other key personnel (including, if applicable, the proposed Teal Postdoctoral Scholar) will ensure success of the proposed work.

- **Environment**
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements, if applicable).
  - How the quality and extent of institutional support are appropriate for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review:** To make funding recommendations, the following 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 innovation
      - Relative impact on ovarian cancer
      - Program portfolio composition and balance
      - Adherence to the intent of the award mechanism

## C.   Recipient Qualification

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

## D.   Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

**E.    Notification of Application Review Results**

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

**IV.    ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

**A.    Rejection**

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.
- Blinding of the pre-application is not followed.

The following will result in administrative rejection of the application:

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

**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 proposed research has overlap with a research project previously awarded to the PI and organization.

- The PI does not meet the eligibility criteria.

## D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

## V. AWARD ADMINISTRATION INFORMATION

### A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### B. Administrative Requirements

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

### C. National Policy Requirements

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

## D.    Reporting

Refer to the General Application Instructions, Appendix 4, Section J, for general information on reporting requirements.  ***Optional Nested Teal Postdoctoral Scholar:***  Progress reports should include an update on the named Teal Postdoctoral Scholar's research training and career progress.

## E.    Award Transfers

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." | |
| | Innovation Statement:  Upload as Attachment 6 with file name "Innovation.pdf." | |
| | Impact Statement:  Upload as Attachment 7 with file name "Impact.pdf." | |
| | Optional Nested Teal Postdoctoral Scholar Statement (if applicable):  Upload as Attachment 8 with file name "ScholarStatement.pdf." | |
| | Letter of Support for the Teal Postdoctoral Scholar (if applicable): Upload as Attachment 9, with file name "ScholarSupport.pdf." | |
| Research & Related Senior/Key Person Profile (Expanded) | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. | |
| | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field. | |
| | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. | |
| | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | Complete as instructed.  Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Project/Performance Site Location(s) Form | Complete form as instructed. | |
| R & R Subaward Budget Attachment(s) Form | Complete form as instructed. | |