Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Outcomes Consortium Development Award

Funding Opportunity Number: W81XWH-12-OCRP-OCDA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 9, 2012
- **Invitation to Submit an Application:** June 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 2, 2012
- **Peer Review:** September 2012
- **Programmatic Review:** November 2012

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Ovarian Cancer Research Program (OCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. Appropriations for the OCRP from FY97 through FY11 totaled $180.45 million (M). The FY12 appropriation is $16M. The overall goal of the FY12 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.

B. Award Information

The OCRP Outcomes Consortium Development Award supports a multi-institutional research effort conducted by leading ovarian cancer researchers and consumer advocates that ***specifically focuses on identifying and understanding predictors of disease outcomes in ovarian cancer patients.*** This effort will be executed through a two-stage approach using two separate award mechanisms: this FY12 Outcomes Consortium Development Award, which will enable the consortium to lay the groundwork for the research project, including proof of concept, and the FY14 Outcomes Consortium Award, which will support the execution of the full research project.

Research projects proposed under the Outcomes Consortium Development Award must focus on predictors of disease outcomes, particularly for ovarian cancer patients who are long-term survivors. The research project should address overarching issues that have broad implications for the disease and risk management, such as risk factors at the individual level and systems level, treatment, toxicity, and dormancy. The research project should not focus merely on the study of specific molecular pathways or genes. The research project should be focused on identifying what is unique to long-term survivors (defined as those who are at least 10 years from initial diagnosis) as compared to short-term survivors.

Applications for the first award, the Outcomes Consortium Development Award, are being requested in this funding opportunity. The Outcomes Consortium Development Award provides support to:

- Develop the infrastructure of the Consortium (e.g., building appropriate collaborations, outlining an administrative and management plan, developing a research and communication plan, and devising an intellectual property plan) and a multi-institutional research team inclusive of scientists, clinicians, and ovarian cancer consumer advocates;
- Acquire research resources (e.g., clinical specimens, epidemiological resources, clinical databases, laboratory expertise, large transcriptome or proteome datasets, and databases of clinical data and/or metadata, reagents, patients);
- Prepare a detailed statistical plan with refined power analysis;
- Demonstrate proof of concept for the proposed research project;

- Prepare documents for obtaining approvals from local Institutional Review Boards (IRBs); and
- Prepare informed consent forms, as applicable.

The Principal Investigator (PI), as the Consortium Director, is expected to have demonstrated experience in successfully leading large, focused research projects. The PI should create an environment that fosters and supports innovation and creativity, with consistent, intensive interaction within the research team in a way that engages all members of the consortium in all aspects of the research project. Scientific participants in this consortium should be scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to the research project. ***The research team must include one or more ovarian cancer consumer advocates who will be integrally involved throughout the planning and implementation of the research project.*** As lay representatives, the consumer advocates must be individuals who have been diagnosed with ovarian cancer and who belong to an ovarian cancer advocacy organization. They must have a high level of familiarity and training involving current issues in ovarian cancer research. Consumer advocates should be involved in the project design, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other consortium members should be well-integrated, ongoing, and not limited to attending seminars and semi-annual meetings.

To develop a multi-institutional ovarian cancer research team, the consortium should include a Coordinating Center at the PI's institution, a sufficient number of Research Sites, and at least one ovarian cancer consumer advocate. The Coordinating Center will establish the necessary collaborations at potential research sites and with the ovarian cancer consumer advocate(s). The Coordinating Center, in addition to functioning as a Research Site, will serve as the consortium's information and planning nexus, providing administrative, operational, and data management support services to participant Research Sites. The Coordinating Center should have extensive experience in developing and conducting multi-institutional research projects. Responsibilities of the Coordinating Center will include protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, intellectual/material property coordination, and a plan for assessment of individual Research Site performance. All Research Sites and the ovarian cancer consumer advocate(s) will be responsible for working collaboratively.

In addition to developing the infrastructure of the consortium and acquiring research resources, the FY12 Outcomes Consortium Development Award provides funding for demonstrating proof of concept. Applicants must submit a statistical plan that includes a preliminary power analysis that reflects sample size projections that will answer the hypothesis and/or objectives of the proposed study. It is expected that this statistical plan and power analysis will be updated in the FY14 Outcomes Consortium Award application.

Recipients of the FY12 OCRP Outcomes Consortium Development Award are expected to submit applications to compete for the Outcomes Consortium Award, which may be offered in FY14 to further support the research efforts. ***Due to the annual appropriations for this program, there is no guarantee that funds will be available to implement this FY14 Outcomes Consortium Award***. The OCRP expects to fund two FY12 Outcomes Consortium Development awards, depending on the number and the quality of applications received. If this goal is not

met, the OCRP then reserves the right to re-release the Outcomes Consortium Development Award funding opportunity or open the FY14 Outcomes Consortium Award to all applicants meeting the eligibility requirements.

FY14 Outcomes Consortium Award Description: A description of the scope and intent of the FY14 Outcomes Consortium Award is provided at this time to assist investigators in preparing applications for the FY12 Outcomes Consortium Development Award. The FY14 Outcomes Consortium Award supports research focused only ***on identifying and understanding predictors of disease outcomes in ovarian cancer survivors.*** The scope of this research effort may include a broad spectrum of research spanning from preclinical to clinical studies, with the end result leading to improved numbers of long-term ovarian cancer survivors. The consortium should comprise a multi-institutional research team made up of scientists and/or clinicians who have made significant contributions in the field of ovarian cancer and at least one consumer advocate associated with an ovarian cancer consumer advocacy organization(s). It is expected that the same research sites and ovarian cancer consumer advocate(s) named in the Outcomes Consortium Development Award application will be included in the Outcomes Consortium Award application. Any changes from the Outcomes Consortium Development Award should be fully justified. Collaborations established through the consortium should be synergistic. The Consortium should maximize the use of resources and minimize unnecessary duplication among consortium members by sharing resources among all consortium members. The OCRP Integration Panel (IP) and CDMRP staff members will serve as an external advisory board for the consortium.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities 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 K.

C. Eligibility Information

- PIs must be independent investigators at the Associate Professor level (or equivalent) or higher.
- Cost sharing/matching is not an eligibility requirement.
- 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 **$400,000** 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., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- The PI and senior/key personnel to give an oral presentation for the FY14 Consortium Award at OCRP Programmatic Review, to be held in the Baltimore/Washington, DC area in early 2015.

May be requested for (not all-inclusive):

- Salary
- Meetings and teleconferences among participating investigators to develop the consortium, including applicable travel costs
- Costs related to identifying and acquiring research resources
- Costs related to demonstrating proof of concept
- Other costs associated with planning and developing the consortium collaborations
- Travel between collaborating organizations
- Travel costs of up to $3,600 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $1.28M of the $16M FY12 appropriation to fund approximately two Outcomes Consortium Development 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 multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-12-OCRP-OCDA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.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 application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

  FY12 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@cdmrp.org or 1-301-682-5507.

  The PI must enter the contact information for all collaborators at each Research Site and the ovarian cancer consumer advocacy organization(s).

- **Required Files – Tab 4**

  Preproposal Narrative (four-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

  The Preproposal Narrative should include the following:

  - A description of the proposed research project that specifically focuses on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors.
  - A statement of the proposed hypothesis or objective(s).
  - A description of the proposed consortium, including key participants at the Coordinating Center, the Research Sites, and the ovarian cancer consumer advocacy organization(s).
  - A description of how the PI's qualifications will enable him/her to lead the proposed consortium.
  - A description of the preliminary power analysis that reflects sample size projections that will address the hypothesis and/or objective(s) of the proposed project.

- A description of the availability of the necessary research resources as determined by the preliminary power analysis, and a brief summary of the plan for acquiring these research resources.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit).
- Letter of Support (one-page limit) from the ovarian cancer consumer advocacy organization(s) that states that the organization(s) will participate in the consortium and outlines its contributions.
- Key Personnel Biographical Sketches (four-page limit per individual).
  - Consortium and Research Site PIs

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

- **Other Documents Tab**

  No additional documents are required.

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the relevance to the mission of the Department of Defense (DoD) and the OCRP, pre-applications will be screened based on the following criteria:

  - How the proposed research project focuses on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors.
  - How the consortium PI's and key participants' qualifications will enable the consortium to conduct the proposed research.
  - How the preliminary power analysis reflects sample size projections that will address the hypothesis and/or objective(s) of the proposed project.
  - How the necessary research resources, as determined by the preliminary power analysis, are available to and accessible by the consortium.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

  Pre-application notification dates are indicated on the title page of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

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/).

Grants.gov application package components: For the Outcomes Consortium Development 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 (12-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed consortium that will focus on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors using the general outline below.

     - Describe previous experience and accomplishments of the PI (Consortium Director) related to the design, administration, and management of multi-institutional research projects.
     - Provide a description of the projected consortium organization. Include key participants at the Coordinating Center, the Research Sites, and the ovarian cancer consumer advocate(s) as well as their projected contributions. Named Research Sites and the ovarian cancer consumer advocate(s) should submit a letter of collaboration.
     - Describe the integral roles that one or more consumer advocate(s) will play in the planning, design, implementation, and evaluation of the proposed research project.
     - Describe the management and communication plan for developing the consortium.
     - Describe the proposed research that focuses on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors. Present the ideas and reasoning behind the proposed research, to include relevant literature citations. State the hypothesis to be tested or the objective(s) to be attained.
     - Describe the preliminary statistical plan for the proposed research project, including the preliminary power analysis that reflects sample size projections that will address the hypothesis and/or the objectives of the project.

- Describe the availability of the necessary research resources as determined by the preliminary power analysis, and a brief summary of the plan for acquiring these research resources. Include how unnecessary duplication of resources among consortium members will be minimized.
- Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.
- Include an estimated duration and the projected direct costs that the FY14 Outcomes Consortium Award will require to answer this critical research question.

- **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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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. 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, reflecting the laboratory space, equipment, and other resources available for the project.
  - Letters of Collaboration: Provide a signed letter from each of the proposed research site PIs and ovarian cancer consumer advocate(s) that describes how he/she will support the consortium PI and the consortium.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."
  - The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- Background: Present the research focus behind the proposed consortium.
- Objective/Hypothesis: State the hypothesis to be tested or the objective(s) to be attained.
- Provide rationale that supports the hypothesis to be tested or the objective(s) to be attained.
- Study Design: Briefly describe the consortium design, organization, and interactions.
- Impact: Summarize briefly how the proposed project will have an impact on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf."
  - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine. Do not duplicate the technical abstract.
  - Describe the ultimate applicability of the consortium's research, including short-term and long-term impact.
    - What are the potential applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
  - How will the development of this consortium enhance and advance the field of ovarian cancer research?
  - How will the proposed research project impact the understanding of the predictors of disease outcomes in long-term ovarian cancer survivors?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.
- **Attachment 6: Impact and Proof of Concept Statement (two-page limit):** Upload as "ImpactProof.pdf."

  Describe the ultimate vision for how the proposed research project, if successful, will have a significant impact on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors. Describe the research plan for the proposed proof of concept study that will generate sufficient data to adequately support this research project when submitted to the FY14 Outcomes Consortium Award funding opportunity.

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

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
    - Include biographical sketches for collaborators at each Research Site.
    - Include biographical sketches for key personnel at the Coordinating Center.
    - Include biographical sketch(es) for consumer advocate(s).
- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - Include current/pending support for collaborators at the Coordinating Center and each Research Site.

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."
5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. 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 any one of the deadlines will result in application rejection.

E. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Numbering System (DUNS) number and register with the Central Contractor Registry (CCR) 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 applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DoD and OCRP, and 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 review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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 Criteria

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

   - **Consortium Structure**
     - Whether the consortium includes a Coordinating Center and Research Sites with named scientists and/or clinicians who have made significant contributions to the field of ovarian cancer or who have specific expertise related to identifying and understanding ovarian cancer predictors of disease outcomes in long-term ovarian cancer survivors.
     - Whether the consortium includes at least one ovarian cancer advocate.
     - How well the infrastructure includes building appropriate collaborations, outlining an administrative management plan, developing a research and communication plan, and devising an intellectual property plan.
     - How well the Coordinating Center and Research Sites will maximize the use of resources and minimize unnecessary duplication of resources.
   - **Personnel**
     - How well the PI's (Consortium Director) qualifications and experience demonstrate appropriate expertise in the design, organization, and management of multi-institutional research projects.
     - How the consortium team's background and expertise are appropriate for accomplishing the goal of identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors.
     - How well the consortium participants are committed to developing a consortium to identify and understand predictors of disease outcomes in long-term ovarian cancer survivors.

- How the consumer advocate(s) are integrally involved in the research and management processes, with appropriate qualifications and background.

- **Research Project**
  - How well the application describes the proposed research project and whether it focuses on identifying and understanding predictors of disease outcomes in long-term ovarian cancer survivors.
  - Whether the application includes a statistical plan and a preliminary power analysis that reflects sample size projection that will address the hypothesis and/or the objective(s) of the proposed project.
  - How the plan for acquiring the necessary research resources is sufficient for the proposed research project.
  - Whether the application outlines how approvals will be obtained from local IRBs and how the informed consent process will be initiated, if applicable.
  - Whether the application includes an estimated duration and projected direct costs for the FY14 Outcomes Consortium Award.
- **Proof of Concept**
  - How the research plan for the proposed proof of concept study will provide sufficient data to adequately support the proposed research project when submitted to the FY14 Outcomes Consortium Award funding opportunity.
- **Impact**
  - How the consortium structure and overall approach will lead to the effective identification and understanding of predictors of disease outcomes in long-term ovarian cancer survivors.

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 influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and OCRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
   - Ratings and evaluations of the peer reviewers
   - Relative impact
   - Adherence to the intent of the award mechanism

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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 notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt 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:

- 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 specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY12 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 document. A list of the FY12 OCRP IP members can be found at http://cdmrp.army.mil/ocrp/panels/panels12.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- 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.

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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the 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: 1-800-518-4726

Email: 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. 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 Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact and Proof of Concept Statement (ImpactProof.pdf) as Attachment 6.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 Current & Pending Support (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.	