# **Program Announcement**

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

# **Ovarian Cancer Research Program**

# **Pilot Award**

Funding Opportunity Number: W81XWH-12-OCRP-PA 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), April 9, 2012
- Invitation to Submit an Application: May 2012
- **Application Submission Deadline:** 11:59 p.m. ET, July 18, 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 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 should include a testable hypothesis based on strong scientific rationale and serve 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.* 

**NEW Areas of Encouragement for FY12:** The Pilot Award accepts applications from all areas of ovarian cancer research, but *encourages* research from the following areas:

- Using novel approaches for improving the performance and validity of predictive disease markers
- Understanding the mechanistic basis of disease markers
- Generating novel imaging/molecular imaging approaches for screening and management
- Generating innovative insights in etiology, risk factors, and outcomes for ovarian cancer
- Identifying and validating molecular targets for therapy

**OCRP Definition of Disease Marker:** A disease marker is a molecular signature, risk factor, or physiological characteristic that associates with the presence, prognosis, or therapeutic response of ovarian cancer.

**OCRP Definition of Innovation:** Innovative ideas for the OCRP are those that, if proven correct, will provide new paradigms, technologies, molecules, *or* applications and that, when applied in the future, will reduce the burden of ovarian cancer.

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. For example, applying a hypothesis previously tested on a different cancer other than ovarian is not considered innovative
- 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 Predoctoral Scholar:** A nested Teal Predoctoral 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 predoctoral student (candidate must be named) can be included as a Teal Predoctoral Scholar within a given application. Applications that contain a nested Teal Predoctoral Scholar will qualify for a higher level of funding as described under the Funding Section below (Section I.D). The mentor may be either the Principal Investigator (PI) or a collaborator on the Pilot Award.

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

- Investigators at the postdoctoral level and above (and equivalent) from academia, research institutions, industry, government agencies, and private foundations are eligible to submit applications.
- For applications with an *optional nested Teal Predoctoral Scholar*: A nested Teal Predoctoral Scholar is defined as a predoctoral student who is currently enrolled full-time in an accredited doctoral program (e.g., Ph.D., M.D., M.D./Ph.D., D.Sc.). In addition, Ph.D., M.D./Ph.D., and D.Sc. candidates must also successfully complete comprehensive examinations or otherwise complete predissertation requirements by the time of award. There are no restrictions for the M.D. candidates. The mentor may be either the PI or a collaborator on the Pilot Award.
- 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 \$250,000 plus indirect costs. If including a qualified nested **Teal Predoctoral Scholar**, the maximum allowable direct costs for the entire period of performance are \$300,000 plus indirect costs. The OCRP reserves the right to reduce funding to the lower level if the nested Teal Predoctoral Scholar does not qualify under the guidelines provided.
- 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:

May be requested for (not all-inclusive):

- Salary
- Stipend
- Tuition
- 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 Predoctoral Scholar to attend ovarian cancer-specific meetings (if applicable)

The CDMRP expects to allot approximately \$3.4M of the \$16M FY12 OCRP appropriation to fund approximately eight 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 multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) application submission through Grants.gov (<a href="https://www.grants.gov/">http://www.grants.gov/</a>).

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 (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) basic search using the Funding Opportunity Number: W81XWH-12-OCRP-PA.

#### B. Pre-Application Submission Content and Form

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 Predoctoral Scholar (if applicable), collaborators, and their organizations(s). Due to the blinded nature of the review process, identifying or making references to the PI, 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 an application. In addition, the use of "I," "we," "our," "this organization," or similar wording in phrases that refer to the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, or their organization(s) through the references listed will also result in administrative rejection of the pre-application and preclude invitation to submit an application.

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 Integration Panel (IP) members should not be involved in any preapplication 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 <a href="help@cdmrp.org">help@cdmrp.org</a> or 1-301-682-5507.

#### • Required Files – Tab 4

**Preproposal Narrative (two-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:

- **Area(s) of Encouragement:** State which of the five Area(s) of Encouragement this application addresses (if applicable). If none are addressed, state "None."
- **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.
- o **Innovation:** Describe how the research is innovative and consistent with the OCRP's definition of innovation. Innovative ideas are those that, if proven correct, will provide new paradigms, technologies, molecules, *or* applications and that, when applied in the future, will reduce the burden of ovarian cancer.

o **Impact:** Describe the potential short-term and long-term impact of this study on ovarian cancer. Research that has high impact will be significant and non-incremental and will move toward eliminating ovarian cancer.

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

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

- Innovation: How the research represents new paradigms, technologies, molecules,
   or applications that, when applied in the future, will reduce the burden of ovarian cancer.
- **Research Idea:** How the proposed work addresses a central problem in ovarian cancer.
- **Impact:** To what degree the proposed study could, whether short-term or long-term, make a significant impact on ovarian cancer.

#### • 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 <u>title page</u> 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 (<a href="http://www.grants.gov/">http://www.grants.gov/</a>). For the Pilot Award, additional application components are also required and should be submitted as directed below.

**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 Project Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Throughout the Project Narrative, describe how the proposed research is innovative, and detail its potential impact on ovarian cancer.

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

Describe the proposed project in detail using the outline below.

- Background: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. *Preliminary 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 the DoD award would fund.
- Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.
- 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 (no page limit): 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 (no page limit per letter): 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 (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 and Material Property Plan (if applicable) (no page limit): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Optional Nested Teal Predoctoral Scholar Statement (if applicable) (two-page limit): The Teal Predoctoral Scholar Statement must be written by the Scholar candidate and should articulate the Scholar's career goals, the proposed training, and how the proposed research training will promote a career in ovarian cancer research. Describe qualifications and achievements that make the predoctoral student the ideal candidate for the Teal Predoctoral Scholar. Describe the Teal Predoctoral Scholar's commitment to a career in ovarian cancer research.
- Letter of Support for the Teal Predoctoral Scholar (if applicable) (no page limit): If a Teal Predoctoral Scholar is proposed, a letter of support from the mentor should describe qualifications and achievements that make the predoctoral student an ideal candidate. The letter should include the statement that the candidate meets eligibility requirements, including successfully completing comprehensive examinations or otherwise completing predissertation requirements by the time of the award. Describe the potential for a successful, committed career in ovarian cancer research.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."
  - o 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.
- o Innovation: Summarize how the proposed research is innovative and, if proven correct, how it will provide new paradigms, technologies, molecules, *or* applications, and, when applied in the future, how it will reduce the burden of ovarian cancer.
- Impact: Describe the potential short-term or long-term impact of the proposed research on ovarian cancer.
- 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.

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.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research:
  - Which individuals will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes.
  - What is the projected time it may take to achieve a clinically relevant outcome?
  - What are the likely contributions of this study to advancing the field of research?
- Attachment 5: Statement of Work (SOW) (two-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.
- Attachment 6: Innovation Statement (one-page limit): Upload as "Innovation.pdf." Summarize how the proposed research is innovative and consistent with the OCRP's definition of innovation; if the proposed research is proven correct, how it will provide new paradigms, technologies, molecules, or applications, and, when applied in the future, how it will reduce the burden of ovarian cancer. Investigating the next logical step or an incremental advancement on published data is not considered innovative.
- Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf." Describe the potential short-term or long-term impact of the proposed research on ovarian cancer. Research that has high impact will, if successful, be significant and non-incremental and will move toward eliminating ovarian cancer.
- **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."
  - o Teal Predoctoral Scholar Biographical Sketch (if applicable).
- Key Personnel Current/Pending Support (no page limit): Upload as "Support LastName.pdf."
- **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 <u>title page</u> 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 Number 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 <a href="http://cdmrp.army.mil/about/fundingprocess.shtml">http://cdmrp.army.mil/about/fundingprocess.shtml</a>. During peer and programmatic reviews, reviewers will <a href="NOT">NOT</a> be blinded to the identity of the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, and their institutions.

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:

#### Innovation

- How the proposed research is innovative and consistent with the OCRP's definition of innovation.
- How the proposed research, if proven correct, will provide new paradigms, technologies, molecules, *or* applications and, when applied in the future, how it will reduce the burden of ovarian cancer.
- How the proposed research represents more than an incremental advance of published data.

## Research Strategy and Feasibility

- How 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 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.

## Impact

How the proposed research will have potential short-term or long-term impact on ovarian cancer.

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

#### Personnel

• How the research team's background, experience, and expertise are appropriate to execute the proposed work.

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

#### Environment

- How the scientific environment is appropriate for the proposed research.
- 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.

#### 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 the Ovarian Cancer Research Program, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:
  - Ratings and evaluations of the peer reviewers
  - Programmatic relevance
  - Relative innovation
  - Relative impact on ovarian cancer
  - Program portfolio balance
  - 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 <u>title page</u> 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.
- Blinding of pre-application is not followed. (Do not identify the PI, collaborators, optional nested Teal Predoctoral Scholar, and/or institutions. Also avoid the use of "I," "our," "this institution," or similar phrases in the Preproposal Narrative that make it possible to identify the PI, collaborators, optional nested Teal Predoctoral Scholar, and/or institutions through any references listed.)

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 <a href="http://cdmrp.army.mil/ocrp/panels/panels12.shtml">http://cdmrp.army.mil/ocrp/panels/panels12.shtml</a>.

- 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.
- The proposed research is, or requests funding for, a clinical trial.
- 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 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: <u>support@grants.gov</u>

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.	
	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
Attachments Form	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 6.	
	Upload Impact Statement (Impact.pdf) as Attachment 7.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
Senior/Key Person Profile (Expanded)	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.	