

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Translational Pilot Award

Funding Opportunity Number: W81XWH-11-OCRP-TPA

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), June 8, 2011
- **Invitation to Submit an Application:** July 2011
- **Application Submission Deadline:** 11:59 p.m. ET, August 18, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** December 2011

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Ovarian Cancer Research Program (OCRP) was established in 1997 to provide support for research of exceptional scientific merit focused on eliminating ovarian cancer. Appropriations for the OCRP from FY97 through FY10 totaled \$160.45 million (M). The FY11 appropriation is \$20M. The overall goal of the FY11 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research.

B. Award Information

The Translational Pilot Award mechanism supports innovative translational research addressing a critical problem or question in ovarian cancer that will accelerate the movement of promising ideas toward clinical applications. The proposed research should provide a catalyst to challenge or expand current thinking about and/or approaches to ovarian cancer. It must involve early-stage translation of an idea from the laboratory to the clinic, or from the clinic back to the laboratory. Observations that generate a translational pilot research idea may be derived from a laboratory discovery, literature review, population-based studies, novel findings from a clinical trial, or a clinician's firsthand knowledge of patients and anecdotal data. Innovation is an important feature of the Translational Pilot Award. ***Preliminary data are not required, but are allowed. The strength of the application should be based on sound scientific rationale and logical reasoning.***

While the ultimate goal of translational research is to move an observation forward into clinical application, translational research is most effective as a two-way continuum between bench and bedside. Within this continuum, the Translational Pilot Award supports early-stage translational research projects. It ***does not support clinical trials***, but may support (1) correlative studies that can be associated with an existing clinical trial, (2) development, validation, and optimization of a novel translational technology, or (3) projects that act as a bridge for clinical study components. Research projects may also include preclinical studies in animal models and/or human biological substances. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found at <http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals>. These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials.

FY11 Areas of Encouragement: The Translational Pilot Award accepts applications from all areas of ovarian cancer research, but ***encourages*** research from the following areas:

- Initiation and precursor lesions in ovarian cancer
- Novel approaches for the evaluation of predictive biomarkers
- Understanding of the host and microenvironment

- Novel imaging approaches for screening and management
- Innovative insights into etiology and risk factors for ovarian cancer

Areas of encouragement that are *NEW for FY11* include:

- Contributions to understanding health disparities in ovarian cancer
- Mechanisms of DNA instability or cellular senescence

The 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 advance 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 cancer different than ovarian cancer 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 part of the Translational Pilot Award to foster the next generation of ovarian cancer investigators through mentored research training. Only one (1) predoctoral student (candidate must be named) can be nested 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 PI or a collaborator on the Translational Pilot Award.

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.). 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 Translational 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 **\$200,000** plus indirect costs. If including a qualified nested **Teal Predoctoral Scholar**, the maximum allowable direct costs for the entire period of performance are **\$250,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- 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.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Stipend
- Tuition
- Research supplies
- Equipment
- Clinical research 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 Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$2.88M of the \$20M FY11 OCRP appropriation to fund approximately 9 Translational 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 (<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 discouraged. The Government reserves the right to 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-11-OCRP-TPA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the Principal Investigator (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 a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

Pre-applications will be screened based on the merit of the proposed research idea, innovation, and impact. Screening of the pre-application will be blinded to the identity of the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, and their institutions – do not identify PI, collaborators, Teal Predoctoral Scholar, or institutions in the pre-application. Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organizations within the Preproposal Narrative is prohibited and will result in administrative rejection of the application. The use of “I,” “our,” “this organization,” or similar wording in phrases that refer to the PI, collaborators, or their organization(s) through any references listed will 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 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**
- **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:

- **Areas of Encouragement:** State which of the seven Areas of Encouragement that 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.
 - **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.
 - **Impact and Translatability:** Discuss how the proposed project involves early-stage translation of an idea from the laboratory to the clinic, or from the clinic back to the laboratory. Describe how the research will accelerate the movement of promising ideas toward clinical applications. State how the proposed research will significantly impact the concepts and methods that will advance the field of ovarian cancer research or impact ovarian cancer patient care.
- **Submit Pre-application – Tab 5**
 - **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 CDMRP, pre-applications will be screened based on the following criteria:
 - **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 and Translatability:** How the proposed project involves early-stage translation of an idea from the laboratory to the clinic, or from the clinic back to the laboratory. How the research will accelerate the movement of promising ideas toward clinical applications. How the proposed research will significantly impact the concepts and methods that will advance the field of ovarian cancer research or ovarian cancer patient care.
- Reminder: 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.**

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

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; 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

PIs will be notified if they are invited to submit an application for the Translational Pilot Award. Applications will not be accepted unless the PI has received an 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 (AOR) through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the Translational 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 **NOT** 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 Department of Defense 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. *Each component has no page limit unless otherwise noted.*
 - 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 (no page limit): 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they 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 pre-dissertation 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."
 - 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, technologies, molecules, or applications, and, when applied in the future, how it will reduce the burden of ovarian cancer.
 - Impact: Describe how the proposed research will impact the concepts and methods that will advance the field of ovarian cancer research or impact ovarian cancer patient care. State explicitly how the research addresses a central problem or question in ovarian cancer that will ultimately accelerate the movement of promising ideas toward clinical applications.
- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

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

Public 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?

- 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 translational research that will be performed through this award. State explicitly how the research addresses a central problem or question in ovarian cancer that will ultimately accelerate the movement of promising ideas toward clinical applications. Explain how the proposed research will significantly impact the concepts and methods that will advance the field of ovarian cancer research or impact ovarian cancer patient care.
- 3. Research & Related Senior/Key Person Profile (Expanded) Form:** 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.”
 - 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 [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall 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, US Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DOD and CDMRP, 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>. *During peer and programmatic reviews, reviewers will **NOT** 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, it is a crime for Federal officials to disclose confidential information of one party to another third party (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 listed in decreasing 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 project and its feasibility, 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 and Translatability**

- How the proposed project involves early-stage translation of an idea from the laboratory to the clinic, or from the clinic back to the laboratory.
- How the research addresses a central problem or question in ovarian cancer.
- How the research will accelerate the movement of promising ideas toward clinical applications and make a significant contribution toward eliminating ovarian cancer.
- How the proposed research will significantly impact the concepts and methods that will advance the field of ovarian cancer research or impact ovarian cancer patient care.

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 demonstrates 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 CDMRP, as well as to make funding recommendations, the following equally considered 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 [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. PIs 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 not followed. 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 organization through any references listed.

The following will result in administrative rejection of the application:

- Project Narrative is missing.
- Project Narrative exceeds page limit.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

B. Modifications

- 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, you 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:

- FY11 OCRP IP member is found to be involved 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 FY11 OCRP IP members may be found at <http://cdmrp.army.mil/ocrp/panels/panels11.shtml>.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The PI does not meet the eligibility criteria.
- The proposed research is, or requests funding for, a clinical trial.

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 US 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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, 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 and 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 Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Innovation (Innovation.pdf) as Attachment 6.	
	Upload Impact (Impact.pdf) as Attachment 7.	
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 form 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.	