Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Ovarian Cancer Research Program

Translational Pilot Award

Funding Opportunity Number: W81XWH-10-OCRP-TPA

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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 Fiscal Year 1997 (FY97) through FY09 totaled \$141.7 million (M). The FY10 appropriation is \$18.75M.

The overall goal of the FY10 OCRP is to eliminate ovarian cancer by supporting innovative, high-impact research. In striving to achieve this goal, the FY10 OCRP is supporting innovative ideas that will drive the field forward and reduce the burden of ovarian cancer in the future. In addition, the OCRP is promoting unique partnerships and fostering the next generation of investigators in ovarian cancer research.

B. Award Description

NEW for FY10, the OCRP 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 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. *Preliminary data are not required, but are allowed. The strength of the proposal 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.

The Translational Pilot Award accepts proposals from all areas of 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

NEW for FY10, the OCRP has a revised definition of innovation. Innovation is an important feature of the Translational Pilot Award. Innovative ideas for the OCRP are those that, if proven correct, will provide totally 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 innovative.
- Using a published series of in vitro assays to further characterize a model system.
- Incorporating known biomarkers into in vitro 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.

The Principal Investigator (PI) is responsible for clearly and explicitly articulating why the proposed research is translational, innovative, and meets the intent of the award mechanism.

Optional Nested Teal Predoctoral Scholar: A nested Teal Predoctoral Scholar is being offered as an optional part of the Translational Pilot Award. The intent of the nested Teal Predoctoral Scholar is to foster the next generation of ovarian cancer investigators through mentored research training of doctoral degree candidates (e.g., Ph.D., M.D., M.D./Ph.D., D.Sc.) who are committed to a career in ovarian cancer. Only one (1) predoctoral student can be nested as a Teal Predoctoral Scholar within a given Translational Pilot Award application. A "To be named" Teal Predoctoral Scholar is not allowed for the application submission. Applications that contain a nested Teal Predoctoral Scholar will qualify for a higher level of funding as described under the Funding Section (Section I.D). These additional funds should be used to support the nested Teal Predoctoral Scholar's participation in this proposed research effort.

Reviewers will be blinded to the identity of the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, and their institutions during the pre-application screening process, but not during peer and programmatic review (See Section III.A).

C. Eligibility

Investigators at all levels 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 meet predissertation requirements by the time of award. There are no restrictions for the M.D. candidates.

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

D. Funding

- The maximum period of performance is 2 years.
- The maximum allowable funding for the entire period of performance is \$200,000 in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 2-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Funding for a Translational Pilot Award that includes a qualified nested **Teal Predoctoral Scholar:**

- The maximum period of performance is 2 years.
- The maximum allowable direct cost amount for the entire period of performance is \$250,000 if the application includes a qualified nested Teal Predoctoral Scholar.

Applications requesting the higher level of funding that do not include a qualified nested Teal Predoctoral Scholar will have their budget reduced as appropriate.

Within the guidelines provided in the General Application Instructions, funds can cover:

- 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.
- Travel costs of up to \$1,800 per year for a nested Teal Predoctoral Scholar to attend ovarian cancer-specific meetings (if applicable)

• Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$4.1M of the \$18.75M FY10 OCRP appropriation to fund approximately 12 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.

E. Award Administration

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. Timeline for Submission and Review

• Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 11, 2010

• Invitation to Submit an Application: April 2010

• Application Submission Deadline: 11:59 p.m. ET, June 10, 2010

• Scientific Peer Review: July 2010

• Programmatic Review: September 2010

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

Submission is a two-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/). *Applications will be invited based on pre-application screening*.

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.

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 eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by 5:00 p.m. ET on the deadline. 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.

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.A. for additional information on pre-application submission.):

Reviewers will be blinded to the identity of the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, and their institutions during the pre-application screening process, but not during the peer and programmatic reviews.

- Proposal Information Tab 1
- Proposal Contacts Tab 2
- Collaborators and Conflicts of Interest (COI) Tab 3
- Required Files Tab 4

Preproposal Narrative (two-page limit): The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The Preproposal Narrative should include the following:

- **Area of Encouragement:** State which of the five Areas of Encouragement that this application addresses (if applicable). If none are addressed, state "None."
- o **Translatability:** Describe how the research addresses a central problem or question in ovarian cancer that will accelerate the movement of promising ideas toward clinical applications.
- o **Innovation**: Describe how the research addresses the FY10 OCRP's definition of innovation: Innovative ideas that, if proven correct, will provide totally new paradigms, technologies, molecules, or applications, and that, when applied in the future, will reduce the burden of ovarian cancer.
- **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 **Impact**: Briefly state how the proposed research will impact the concepts and methods that drive the field of ovarian cancer research, and how, if successful, it will make a significant contribution toward eliminating ovarian cancer.

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

- References Cited (one-page limit): List relevant references 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). The inclusion of Internet URLs to references is encouraged.
- Submit Pre-Application Tab 5
- Other Documents Tab Not applicable

Pre-Application Screening: Pre-applications will be screened by the OCRP Integration Panel, which is composed of scientists, clinicians, and consumer advocates. Due to the blinded nature of the screening process, identifying or making references to the PI, nested Teal Predoctoral Scholar (if applicable), collaborators, or their institutions within the Preproposal Narrative is prohibited and will result in administrative rejection of the pre-application and preclude invitation to submit a full application.

The pre-application screening criteria are as follows:

- **Translatability:** How the research addresses a central problem or question in ovarian cancer that will accelerate the movement of promising ideas toward clinical applications.
- **Innovation**: How the research represents totally 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**: How the proposed research will impact the concepts and methods that drive the field of ovarian cancer research and how, if successful, it will make a significant contribution toward eliminating ovarian cancer.

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., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

PIs will receive notification of invitation to submit an application for the Translational Pilot Award. Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (http://www.grants.gov/). Applications must be submitted by 11:59 p.m. ET on the deadline.

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

1. SF 424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section II.B., for detailed information.

2. Attachments Form

• Attachment 1: Project Narrative (6-page limit): Upload as "ProjectNarrative.pdf."

Throughout the Project Narrative, describe how the proposed research is innovative, and detail its potential impact on ovarian cancer research. *Preliminary data are not required, but are allowed.* However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. *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.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- 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 biological 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: List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
 - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
 - 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): 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 resources necessary for the proposed work.
- Intellectual and Material Property Plan (if applicable): 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 proposed Teal Predoctoral Scholar Statement must be written by the Scholar and should articulate the Scholar's career goals 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, then one Letter of Support should be provided from the primary mentor. The letter of support should describe qualifications and achievements that make the predoctoral student the ideal candidate for the Teal Predoctoral Scholar. Describe the potential for a successful 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: Briefly describe the study design including appropriate controls.
 - o Innovation: Briefly summarize how the proposed research is innovative and, if proven correct, how it will provide totally new paradigms, technologies, molecules, or applications, and, when applied in the future, how it will reduce the burden of ovarian cancer.

- Impact: Briefly describe how the proposed research will impact the concepts and methods that drive the field of ovarian cancer research and how, if successful, it will make a significant contribution toward eliminating ovarian cancer.
- 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.
 - o Which individuals will it help, and how will it help them?
 - o 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.B., for detailed information.

- Attachment 6: Detailed Budget and Justification (no page limit): Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit): Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.
- Attachment 8: Innovation Statement (one-page limit): Upload as "Innovation.pdf." Summarize how the proposed research is innovative and, if proven correct, how it will provide totally 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 9: Impact Statement (one-page limit): Upload as "Impact.pdf." Explain how the proposed research will impact the concepts and methods that drive

- the field of ovarian cancer research, and how, if successful, it will make a significant contribution toward eliminating ovarian cancer.
- Attachment 10: Translatability Statement (one-page limit): Upload as "Translatability.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.
- **3.** Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., 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. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and 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 may be found at http://cdmrp.army.mil/fundingprocess.htm. 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.

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. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are of decreasing importance:

• Innovation

- How the proposed research is innovative and, if proven correct, how it will
 provide totally 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.

Translatability

- How the research addresses a central problem or question in ovarian cancer that will accelerate the movement of promising ideas toward clinical applications.
- 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.

• 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 acknowledges potential problems and addresses alternative approaches.

Impact

 How the proposed research will impact the concepts and methods that drive the field of ovarian cancer research and how, if successful, it will make a significant contribution toward eliminating ovarian cancer.

The following will not be individually scored, but may impact 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, 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

- How the writing and components of the application influenced the review.
- **2. Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations.
 - Ratings and evaluations of the peer reviewers
 - Programmatic relevance
 - Relative innovation, translatability, and impact
 - Program portfolio balance
 - Adherence to the intent of the award mechanism

V. 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

• 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 the references listed.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- 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 V-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 application:

- FY10 OCRP Integration Panel (IP) member(s) 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 FY10 OCRP IP members may be found at http://cdmrp.army.mil/ocrp/panel10.htm.
- 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 detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested 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.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507 Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 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 according to General Application Instructions	
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 Detailed Budget and Justification (Budget.pdf) as Attachment 6 Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7 Upload Innovation Statement (Innovation.pdf) as Attachment 8 Upload Impact Statement (Impact.pdf) as Attachment 9 Upload Translatability Statement (Translatability.pdf)	
Research & Related Senior/Key Person Profile (Expanded)	as Attachment 10 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	
Project/Performance Site Location(s) Form	Complete form according to General Application Instructions	