Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Impact Award

Funding Opportunity Number:  W81XWH-10-PCRP-IA

TABLE OF CONTENTS

I. Funding Opportunity Description ................................................................. 2
   A. Program Description .................................................................................. 2
   B. Award Description .................................................................................... 3
   C. Eligibility ..................................................................................................... 4
   D. Funding ........................................................................................................ 4
   E. Award Administration ................................................................................ 5
II. Timeline for Submission and Review ............................................................... 5
III. Submission Process .......................................................................................... 5
    A. Step 1 – Pre-Application Components ....................................................... 5
    B. Step 2 – Application Components ............................................................. 7
IV. Information for Application Review .................................................................. 10
    A. Application Review and Selection Overview ............................................. 10
    B. Review Criteria .......................................................................................... 11
V. Administrative Actions ...................................................................................... 13
VI. Contact Information ......................................................................................... 14
VII. Application Submission Checklist ................................................................ 15
I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY09 totaled $970 million (M). The FY10 appropriation is $80M.

The overall goal of the FY10 PCRP is to find and fund innovative, high-impact research that will eliminate death and suffering from prostate cancer. Specifically, the PCRP seeks to:

- Support innovative high-risk, high-gain research with potential near-term impact;
- Sponsor multidisciplinary synergistic research;
- Fund translational studies to promote the fluid transition of knowledge between bedside and bench;
- Invest in research on patient survivorship (quality of life);
- Foster the next generation of prostate cancer investigators through mentored research; and
- Promote research into prostate cancer health disparities.

New for FY10: PCRP Overarching Challenges

The overarching goals of the FY10 program are aimed towards eliminating death and suffering from prostate cancer. All applications for the PCRP Impact Award should address at least one of these overarching challenges:

- Develop effective treatments for advanced prostate cancer
- Distinguish lethal from indolent disease

PCRP Focus Areas (revised for FY10)

Applications for the PCRP Impact Award should also address at least one of the following FY10 PCRP focus areas:

Biomarkers: Discovery and validation of biomarkers for the detection, prognosis, and progression of prostate cancer.

Genetics: Understanding the genetics and epigenetics responsible for susceptibility, disease progression, and treatment outcomes for clinically significant prostate cancer.

Imaging: Development of new imaging technology for the detection and prognosis of prostate cancer, including progression to systemic disease.

Survivorship: Studies on the impacts of treatment, nutrition, metabolism, and exercise on the well being of prostate cancer patients and their families.

Therapy: Identification of new targets, pathways, and therapeutic modalities or molecules for the treatment of prostate cancer.

Tumor Biology: Understanding the heterogeneity and microenvironment for the prognosis and progression of prostate cancer.
B. Award Description

The PCRP Impact Award mechanism is being offered for the first time in FY10. This award will support research projects specifically focused on making a major impact on one critical issue in prostate cancer: Reducing or eliminating the over-treatment of primary prostate cancer. Projects funded by this award will, if successful, ultimately change the standard of practice for decision-making in the treatment of primary prostate cancer.

Studies conducted under the Impact Award may involve the development of surveillance mechanisms, including improvements in current clinical and diagnostic tools to monitor prostate cancer patients. Proposed projects may include basic, translational, or clinical research, including clinical trials, provided the overall project is hypothesis-based and focused on the problem of prostate cancer over-treatment. It is expected that clinical studies would include longitudinal follow-up to differentiate, at the time of diagnosis, between patients whose disease is indolent and those whose disease will progress to the lethal phenotype. It is anticipated that studies supported by the Impact Award will facilitate assessment of the decision-making process for early stage prostate cancer using clinically relevant endpoints such as progression and need for treatment.

Research proposed under the Impact Award may include, but is not limited to, the following topic areas that will address the over-treatment of primary prostate cancer:

- Active surveillance (e.g., to standardize inclusion/exclusion criteria)
- Biomarkers
- Genetic Analysis
- Improved staging and grading, to include imaging
- Optimal measures for decision making pre- and post biopsy
- Optimal measures for follow-up and assessment of progression
- Cancer care outcomes research (e.g., quality of life, survivorship) and surveillance

Principal Investigators (PIs) applying for the Impact Award are expected to establish a multi-disciplinary study team that may include a variety of clinical specialists to effectively address the proposed question. A robust statistical plan and statistical expertise should be included in the proposed investigation.

Due to this award’s emphasis on impact, applications must include preliminary data to support feasibility of the study. Any preliminary data provided should be from the laboratory of the PI or member(s) of the research team.

*Research involving human subjects, including clinical trials, is permitted under this Program Announcement/Funding Opportunity. If the proposed study involves clinical research (including clinical trials), it is expected that regulatory approval will be obtained and the research initiated within the first year of the award.* Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects data, or human anatomical substances.
It is the responsibility of the PI to clearly and explicitly articulate how the project addresses the following important aspects of the Impact Award:

**Research Question:** Research proposed under the Impact Award must specifically address the reduction or elimination of over-treatment of primary prostate cancer. The proposed work must be based on a sound overall research strategy and may be from any discipline or combination of disciplines. If the study proposed is addressed from a population-based perspective, applications should include a clearly defined population and evidence of appropriate access to the population.

**Impact:** The proposed research must have the potential to revolutionize clinical care of prostate cancer such that the over-treatment of primary disease will be significantly reduced or eliminated.

**C. Eligibility**

Applicants must be independent investigators at or above the level of Assistant Professor (or equivalent). Refer to General Application Instructions, Appendix 1, for general eligibility information.

**D. Funding**

- The maximum period of performance is 4 years.
- The maximum allowable funding for the entire period of performance is $750,000 in direct costs.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 4-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.

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

- Salary
- Research supplies
- Equipment
- Purchase of datasets and/or databases
- Clinical research costs
- Travel between collaborating organizations
- Travel costs of up to $3,600 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

In addition, funding must be requested for the PI to travel to one 3½-day PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.
The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.4M of the $80M FY10 PCRP appropriation to fund approximately two Impact 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 17, 2010
- Invitation to Submit an Application: April 19, 2010
- Application Submission Deadline: 11:59 p.m. ET, June 9, 2010
- Scientific Peer Review: July/August 2010
- Programmatic Review: October 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/). A letter of invitation is mandatory for submission of an application. 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 for additional information on pre-application submission.)

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – 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:

  - **Rationale:** 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. Clearly describe how the research question addresses an issue of critical significance to the problem of over-treatment of prostate cancer.
  - **Research Strategy:** Concisely describe the project’s specific aims.
  - **Impact:** Describe the potential of the proposed study to have a revolutionary impact towards reducing or eliminating the over-treatment of primary prostate cancer.
  - **Overarching Challenges and Focus Areas:** State how the proposed study is responsive to at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.

**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.
  - **List of Acronyms and Symbols:** Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
  - **Biographical Sketches for the PI and Key Personnel (four-page limit per individual)**

- **Submit Pre-application – Tab 5**
- **Other Documents Tab** (not applicable)

**Pre-Application Screening:** Pre-applications will be screened by the PCRP Integration Panel (IP). PIs whose pre-applications meet the intent of the award mechanism will be invited to submit applications. Following pre-application screening, PIs will be notified regarding 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

*Applications will not be accepted unless the PI has received a letter of invitation.*

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.

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.

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 (15-page limit):** Upload as “ProjectNarrative.pdf.”

   Describe the proposed project in detail using the outline below. The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by preliminary data and published reports. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

   Throughout the Project Narrative, clearly convey how the proposed research, if successful, would have a major impact on the over-treatment of primary prostate cancer.

   - **Background:** Present the ideas and reasoning behind the proposed research. Cite relevant literature. Describe previous experience most pertinent to this proposal.

   - **Hypothesis:** State the hypothesis to be tested or the objective to be reached.

   - **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.

   - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Statistical analyses appropriate to the type of study (e.g., power analysis for population-based studies) should be well described.
○ **Clinical Studies (if applicable):** If the proposed clinical study is prospective, discuss plans for initiating the clinical study within the first year of the award. Provide a properly powered statistical plan and information demonstrating that a sufficient number of participants will be accrued to the proposed study during the award period. Describe relevant ethical considerations, including risk versus benefit of participation in the study. The PI or research team must demonstrate appropriate expertise in conducting clinical studies.

○ **Strategic Plan:** Provide an overall strategic plan for completing the proposed project. If the entire project will not be completed during the performance period of the award, provide evidence that sufficient funds will be available to complete the project. For prospective clinical studies, describe and/or provide evidence that the research can be initiated within the first year of the award.

○ **Research Team:** Describe the expertise and specific contributions of the multidisciplinary research team that will enable the success of the proposed project.

○ **Overarching Challenges and Focus Areas:** Briefly state how the proposed research addresses at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.

• **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: 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: 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) (two-page limit per letter): Provide a signed letter from each collaborator that describes how he/she will support the project, to include:
- Unique expertise,
- Availability of and access to research resources, and/or
- Availability of and access to appropriate populations (if applicable).

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

Technical abstracts should be written using the outline below.
- 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.
- Impact: Summarize how the proposed research project, if successful, will revolutionize the understanding and/or clinical care of prostate cancer such that the problem of over-treatment will be reduced or eliminated.
- Overarching Challenges and Focus Areas: State how the proposed project addresses at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.

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.
  - What types of patients 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 patient-related outcome?

Attachment 5: Statement of Work (SOW) (three-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: Impact Statement (one-page limit):** Upload as “Impact.pdf.” Describe the ultimate vision for how the proposed work, if successful, will have a revolutionary impact on reducing or eliminating the problem of over-treatment of prostate cancer.

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.”
   - 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](http://cdmrp.army.mil/fundingprocess).

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 nondisclosure 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 equally important.
   - **Impact**
     - To what degree the proposed project, if successful, will reduce or eliminate over-treatment of primary prostate cancer.
     - To what degree the proposed research, if successful, would revolutionize the understanding and/or clinical care of prostate cancer.
   - **Research Strategy and Feasibility**
     - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
     - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
     - How well the PI acknowledges potential problems and addresses alternative approaches.
     - Whether the application includes an appropriate statistical plan with power analysis (if applicable).
     - Whether the PI has provided sufficient evidence to support availability of and access to the populations/samples required for the study (if applicable).
     - Whether the PI has provided sufficient evidence that resources will be available to complete longitudinal follow-up beyond the period of performance (if applicable).
     - For clinical studies, whether the PI has sufficiently demonstrated that the research can be initiated within the first year of the award.
   - **Personnel**
     - Whether the PI meets the eligibility requirements for this mechanism.
     - To what degree the research team’s background and prostate cancer-related expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise.
○ To what degree the levels of effort are appropriate for successful conduct of the proposed work.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Ethics and/or Regulatory Issues**
  ○ Whether issues regarding ethics, information privacy, and assessment of risk versus benefit of participation have been adequately considered (if applicable).

- **Environment**
  ○ To what degree the scientific environment is appropriate for the proposed research.
  ○ How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
  ○ To what degree the quality and extent of organizational support are appropriate for the proposed research.

- **Responsiveness to Overarching Challenges and Focus Areas**
  ○ Whether the proposed research project is responsive to at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.

- **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.

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the PCRP overarching challenges and focus areas
- Ratings and evaluations of the peer reviewers
- Relative impact
- Program portfolio composition
V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from 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 exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

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 and Preproposal 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 PCRP Integration Panel (IP) member(s) is found to be involved in the preapplication 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 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panel10
- 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

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<th>Grants.gov Application Components</th>
<th>Action</th>
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<td>Attachments Form</td>
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