

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Prostate Cancer Research Program

Laboratory-Clinical Transition Award

Funding Opportunity Number: W81XWH-10-PCRP-LCTA

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## 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 goals of the FY10 PCRP are aimed towards eliminating death and suffering from prostate cancer. All applications for the PCRP Laboratory Clinical Transition Award must address at least one of the following PCRP overarching challenges:

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

#### **PCRP Focus Areas (*revised for FY10*)**

Applications for the PCRP Laboratory Clinical Transition Award must 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 PCRFP Laboratory Clinical Transition Award mechanism was introduced in FY07. Since then, 36 applications have been received, and 6 have been recommended for funding.

The Laboratory Clinical Transition Award supports goal- and product-driven preclinical studies of promising lead agents that have the potential to revolutionize prostate cancer clinical care. This award is intended to fund PIs who lack support to conduct the preclinical studies needed to advance lead agents to human testing. The goal of this award is the generation of pharmacology and toxicology data for inclusion in a U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) application prior to current Good Manufacturing Practice (cGMP) production of the lead agent(s). Agents supported by this award mechanism are expected to have high potential for commercial licensing for continued development and clinical use.

Applicants are expected to have a validated target, and to have identified either one lead agent or a limited number of lead agents for optimization before applying for this award. In addition, the PI should present data establishing the mechanism of action of the lead agent(s) on the target. ***Lead agents are defined as novel biological, molecular, or chemical therapeutics or imaging agents, that have potential clinical application to prostate cancer.*** Examples of lead agents include, but are not limited to: novel chemotherapeutics, antibodies, nanoparticles, and imaging contrast agents.

Proposals must include preliminary data relevant to the lead agent(s) under development. ***Preliminary data must document target availability and distribution in relevant human tissues, and must provide substantive information from model systems that supports the potential efficacy of the lead agent(s) in humans.***

The National Cancer Institute (NCI) has constructed developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism. These pathways are comprehensive and span the entire translational research continuum from discovery of a target to clinical trials ([http://www.cancer.gov/images/trwg/Developmental-Pathway-Agent-Drug\\_Biologics.pdf](http://www.cancer.gov/images/trwg/Developmental-Pathway-Agent-Drug_Biologics.pdf)). Please note that the focus of this award is to support the development of the lead agent(s) up to but not including cGMP production of the agent.

***Studies proposed under this award may include, but are not limited to:***

- Comparative activity/efficacy testing to optimize a lead agent and/or define a single lead agent from a limited library of candidates. ***Such studies must be completed within 12 months of the start date of the award. If the studies are not completed within 12 months of award initiation, the government reserves the right to terminate the award.***
- Toxicology screening
- Pharmacokinetics (e.g., absorption, distribution, metabolism, and excretion) studies
- Pharmacodynamic studies
- Radiation dosimetry

- Development and validation of assays and reagents required to measure biological responses and molecular endpoints of the lead agent; ***such studies may only be proposed in conjunction with lead agent development***
- Combination of the lead agent with agents already in clinical testing or practice

***Studies proposed under this award should not include:***

- Target discovery
- Drug screening
- Development of devices
- New combinations, formulations, or modifications of agents already in clinical testing or practice (other than in combination with the lead agent)
- Mechanism of action studies
- Prevention agents

***Projects involving human subjects or specimens will be supported only if they are exempt under Title 32 of the Code of Federal Regulations Section 219.101(b) (4) (32 CFR 219.101(b) (4)) or qualify for expedited review under 32 CFR 219.110 or 21 CFR 56.1102. Clinical trials are not allowed.*** In general, a clinical trial is defined as a prospective study where an intervention (e.g., device, drug, behavioral, surgical procedure, or other) is tested on human subjects for a measurable outcome. Additional information on the protection of human subjects and exempt or expedited review status may be found at [https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/\\$file/Title\\_32\\_CFR\\_Part\\_219.pdf](https://www.bids.tswg.gov/TSWG/bids.nsf/5DD5E2BA50F02C18852572B1005F5B8B/$file/Title_32_CFR_Part_219.pdf). ***Applications proposing studies that do not qualify for exempt or expedited review status will be administratively withdrawn.***

The preclinical drug development process may require resources beyond those available at a single laboratory or organization. As such, the PI must disclose any patents issued or pending, and/or licenses granted and/or pending, with respect to the lead agent(s) as well as any known patents that may block the development of the lead agent(s). The PI must provide documentation, such as a Material Transfer Agreement, of access to and permission to use all intellectual and material property. Participating organizations must be willing to resolve potential intellectual and material property issues, and to remove organizational barriers that might interfere with the cooperation necessary to ensure that the proposed studies can be completed.

PIs are expected to abide by the FDA existing and proposed guidances governing the conduct of preliminary studies and the collection of data in support of an IND application (refer to [http://www.fda.gov/cder/regulatory/applications/ind\\_page\\_1.htm](http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm)).

***Applications must describe statistical analyses to support the proposed studies. Statistical analyses must be consistent with current FDA guidance.***

### **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 **3** 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 3-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
- Clinical research costs (Other than costs for clinical trials, which are not allowed.)
- Travel between collaborating organizations
- Travel costs of up to \$1,800 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 PCRPA 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 PCRPA appropriation to fund approximately two Laboratory-Clinical Transition 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), May 5, 2010**
- **Application Submission Deadline: 11:59 p.m. ET, May 26, 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/>).

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](mailto: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.**

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**

**Letter of Intent (LOI) Narrative (one-page limit):** Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only (e.g., reviewer recruitment) and ***will not be reviewed*** during either the peer or programmatic review sessions.

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

## B. Step 2 – Application Components

***Applications will not be accepted unless the pre-application process is completed by the pre-application deadline.*** 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 (25-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below. ***The inclusion of preliminary data relevant to the target, lead agent, and mechanism of action is required.*** Please be aware that the Laboratory Clinical Transition Award supports research only from the identification of a lead agent up to but not including cGMP production of the agent.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
- **Target and Lead Agent(s):** Describe the target, the lead agent(s) and its clinical utility, and the mechanism of action of the agent on the target. Indicate whether the lead agent(s) are being developed in partnership with another organization, and the nature of the partnership.
- **Objective:** State the overall objective(s) 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 for preclinical validation of the lead agent(s) under development. Describe in detail the methods and analyses, including appropriate controls, a timeline for the completion of each proposed task, and how the approaches are compliant with FDA guidance for IND application. Address potential problems 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. ***This award may not be used to conduct clinical trials.***

- **Overarching Challenges and Focus Areas:** Describe (a) how the proposed research addresses at least one of the PCRP overarching challenges *and* (b) how the proposal is responsive to 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 collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
  - Patents and Permissions (if applicable): Disclose any patents, issued or pending, and/or licenses, granted and/or pending, with respect to the lead agent(s) as well as any known patents that may block the development of the lead agent(s). The PI must provide documentation of access to and permission to use all intellectual and material property.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Technical abstracts should be written using the outline below.
  - Background: Present the ideas and reasoning behind the proposed work. Briefly describe the lead agent(s), target, and mechanism of action.

- Objective: State the goals to be achieved. Provide the rationale to support achievement of the stated goals.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Briefly describe how the proposed project and the lead agent to be developed will have an impact on the elimination of death and suffering from prostate cancer.
- Overarching Challenges and Focus Areas: Summarize how the proposed project addresses at least one of the PCRP overarching challenges and at least one of the PCRP focus areas.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
  - 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?
  - 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: Impact Statement (one-page limit):** Upload as “Impact.pdf.”  
State explicitly how the proposed work and the lead agent to be developed will, if successful, have an impact on prostate cancer research and/or clinical care, and how the expected results of the project will contribute to the goal of eliminating death and suffering from 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>

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. Of these, Lead Agent(s), Research Strategy, and Clinical Impact are the most important.

- **Target, Lead Agent(s), and Mechanism of Action**
  - To what extent the development of the lead agent(s) is justified by a sound scientific rationale that is supported by a critical analysis of the relevant literature, preliminary data, and logical reasoning.

- Whether the PI has identified a well-defined target, and how well the preliminary data support the validity of the target for prostate cancer.
- To what extent the PI has clearly documented, with supporting preliminary and/or published data, that the mechanism of action of the lead agent(s) on the target has been established.
- **Research Strategy and Feasibility**
  - Whether the study has the potential of developing a viable lead agent that would be ready for cGMP production.
  - If applicable, whether the PI has presented a clear and feasible plan to narrow a small library of potential lead agents to one lead agent within the first 12 months after award initiation.
  - How well the objectives, aims, experimental design, methods, and analyses are developed.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether the proposal includes a clear and appropriately powered statistical plan.
  - How well the research strategy complies with FDA recommendations for nonclinical studies in support of IND submissions.
  - If applicable, whether the PI has presented an Intellectual and Material Property Plan sufficient to resolve potential issues among participating organizations, including the acknowledgement of and compliance with relevant patents and permissions.
- **Clinical Impact**
  - To what extent the lead agent(s), if successfully developed, will have a major impact on prostate cancer clinical care, including the likelihood for commercial licensing and the elimination of death and suffering from prostate cancer.
- **Personnel**
  - 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.
  - To what degree the levels of effort are appropriate for successful development of the lead agent(s).
  - Whether letters of collaboration are provided for any proposed collaborative arrangements (as applicable).

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

- **Responsiveness to Overarching Challenges and Focus Areas**
  - Whether the proposed research project responds to at least one of the PCRCP overarching challenges and at least one of the PCRCP focus areas toward the goal of eliminating death and suffering from prostate cancer.
- **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 collaborative arrangements).
  - To what degree the quality and extent of organizational support are appropriate.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **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 PCRCP 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 CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

### A. Rejection

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).
- Pre-application is not submitted.

## **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 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 proposed research includes a clinical trial.
- 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](mailto: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](mailto: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](mailto: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<br>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 Detailed Budget and Justification (Budget.pdf) as Attachment 6  |           |
|   | Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7                           |           |
|   | Upload Impact Statement (Impact.pdf) as Attachment 8   |           |
| 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 |           |
| Project/Performance Site Location(s) Form               | Complete form as instructed  |           |