Program Announcement

Department of Defense (DOD) Prostate Cancer Research Program (PCRP)

Funding Opportunity Number: W81XWH-07-PCRP-LCTAI

Laboratory-Clinical Transition Award: Stage I

I. HELP LINE INFORMATION

A. Agency Name

US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

B. Agency Contact(s)

1. **Program announcement, proposal format, or required documentation:** Principal Investigators (PIs) and Authorized Organizational Representatives (AORs) should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

2. **eReceipt system:** A help line for questions relating to the submission of pre-application components through the CDMRP eReceipt system is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by email as follows:

Website: https://cdmrp.org
Email: help@cdmrp.org

3. **Grants.gov:** Issues in submitting applications through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov at 800-518-4726 or email support@grants.gov. The Grants.gov hours of operation are Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time. Deadlines for proposal submission are set at 11:59 p.m. Eastern Time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov Help Desk will NOT be available to assist with Grants.gov submissions. Please plan ahead accordingly, as the CDMRP Help Desk is not able to answer questions about Grants.gov submissions.

Grants.gov will only notify PIs of changes made to this Program Announcement and/or Application Package if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. Please note that if the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

C. Anticipated Instrument Type(s)

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request via:

Fax: 301-619-2937
Email: qa.baa@amedd.army.mil

D. Catalog of Federal Domestic Assistance (CFDA) Number 12.420

Military Medical Research and Development.

E. Commonly Made Mistakes

- Pre-application submission is not completed before the mandatory pre-application deadline (pre-application remains in draft status).
- Failure to request updates on any modifications made to the application package.
- Incorrect application package or award mechanism is used to submit a proposal through Grants.gov.
- Attachments are uploaded into the incorrect form on Grants.gov.
- Files are attached in the wrong location on Grants.gov forms.
- Attachments are not PDF documents.
- Page limitations are exceeded.

II. FUNDING OPPORTUNITY DESCRIPTION

Funding of proposals received in response to this program announcement is contingent on the availability of Federal funds appropriated in a bill for this program.

A. Award Description

The Prostate Cancer Research Program (PCRP) Laboratory-Clinical Transition Award: Stage I supports ***goal- and product-driven*** preclinical studies of promising lead agents that have the potential to revolutionize prostate cancer clinical care. The Laboratory-Clinical Transition Award: Stage II, to be offered in Fiscal Year 2010 (FY10) pending availability of funds, will be described briefly at the end of this section.

The Stage I 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 sufficient data to justify inclusion of lead agents into future clinical trials for the prevention, detection, or treatment of prostate cancer.

For the purposes of the Stage I Award, ***lead agents are defined as biological or chemical therapeutics, imaging agents, or preventive agents that have potential clinical application to prostate cancer.*** Examples of lead agents include but are not limited to: novel chemotherapeutics, antibodies, viral particles, and contrast agents. ***PIs are expected to have identified either one lead agent or a limited number of lead agents for optimization before applying for this award.***

All Stage I Award proposals must include preliminary data relevant to the lead agent(s) under development. ***Preliminary data must provide information regarding target availability and distribution in relevant human tissues and must support the efficacy of each agent in model systems.***

Studies that may be funded under this award include, but are not limited to:

- comparative activity/efficacy testing to 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, funding for the award will be terminated.***
- toxicology screening
- drug metabolism, biodistribution, and pharmacokinetic assays
- pharmacodynamic studies
- radiation dosimetry
- development and validation of assays and reagents required to measure biological responses and molecular endpoints

Studies that may NOT be funded under this award include, but are not limited to:

- target discovery
- drug screening
- development of devices
- development of serum- or tissue-based biomarkers for the primary diagnosis of disease
- new combinations or formulations of conventional therapeutics

Preclinical studies 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. Studies that do not qualify for exempt status or expedited review will be administratively withdrawn and will not be funded.

The preclinical drug development process may require resources beyond those available at a single laboratory or institution. 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 block the development of the lead agent(s). In the event that the project requires the use of a non-commercially available technology/material that is patented by a third party, the PI must provide documentation that the third party patent holder does not object to the PI's use (see Appendix 3). Participating institutions must be willing to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure that the intent of the mechanism is met.

In addition, a clear and appropriately powered statistical plan for lead agent development must be included in the proposal.

Since the ultimate goal of translational research is to obtain Investigational New Drug (IND) approvals on lead agents, PIs are expected to abide by US Food and Drug Administration (FDA) proposed and existing regulations 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). Please note that the focus of the Stage I Award is to support the optimization of an identified lead agent up to but not including current Good Manufacturing Practice (cGMP) production of the agent.

Laboratory-Clinical Transition Award: Stage II

The Stage II Award will facilitate and expedite the bench-to-bedside transition of promising lead agents by funding:

- Full-scale cGMP production of the agent for clinical trials.
- Studies with the cGMP-produced agent (e.g., toxicology and pharmacology) to support an IND application (or equivalent) to the FDA or other regulatory agency.

All PIs funded by the Stage I Award who have viable lead agents are encouraged to compete for the Stage II Award, which is anticipated to be offered in FY10 pending receipt of appropriations.

The Stage II Award will also be open to PIs who have not submitted to or been funded by the FY07 Stage I Award.

Full guidance regarding the format and content of the Stage II Award proposal will be provided in the Program Announcement for the Stage II Award.

Please note that there is no guarantee that funds will be available for the Laboratory-Clinical Transition Award: Stage II.

B. Eligibility

PIs at all academic levels (or equivalent) are eligible to submit proposals. Additional information about individual and institutional eligibility may be found in Appendix 1.

C. Funding

Funding for a Laboratory-Clinical Transition Award: Stage I can be requested for up to $750,000 for direct costs for up to a 3 year performance period plus indirect costs as appropriate. When the applicant institution calculates its own indirect costs for subawards, it can only charge indirect costs on the first $25,000 of each subaward.

Funds can cover:

- salary
- research supplies
- equipment
- travel to scientific/technical meetings
- travel between collaborating institutions

In addition, funding must be requested for each investigator for travel to the next PCRP Innovative Minds in Prostate Cancer Today (IMPaCT) Meeting (tentatively scheduled for 2010).

Funds from this award may not be used to support clinical trials. Other projects involving human subjects or specimens will be supported through this mechanism only if they are exempt under 32 CFR 219.101(b) (4) or qualify for expedited review under 32 CFR 219.110 or 21 CFR 56.1102. Studies that do not qualify for exempt status or expedited review will be administratively withdrawn and will not be funded.

The nature of the PCRP does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted.

The CDMRP expects to allot approximately $5.4 million (M) of the $80M Fiscal Year 2007 (FY07) PCRP appropriation to fund approximately 4 Laboratory-Clinical Transition Award: Stage I proposals, depending on the quality and number of proposals received.

D. Award Administration

A change in PI is not allowed for the Laboratory-Clinical Transition Award: Stage I mechanism. A change in institutional affiliation will require the PI to resubmit the entire proposal packet through his or her new institution. The PI's original institution must agree to relinquish the award.

E. Submission and Review Timeline

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) proposal submission.

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time, April 26, 2007**
- **Proposal Submission Deadline: 11:59 p.m. Eastern time, May 16, 2007**
- **Peer Review: July 2007**
- **Programmatic Review: October 2007**

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2008.

III. PROGRAM HISTORY AND OBJECTIVES

The PCRP was established in FY97 to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY06 totaled $730M. The FY07 appropriation is $80M. The Laboratory-Clinical Transition Award: Stage I mechanism is being offered for the first time in FY07.

The overall goal of the FY07 PCRP is to find and fund innovative, high-impact research that seeks to (1) prevent prostate cancer, (2) detect and diagnose prostate cancer in its earliest stages of development, and (3) treat prostate cancer.

The FY07 PCRP is focusing on the following areas of programmatic interest:

- Animal Models
- Basic Biology of the Prostate
- Biomarkers
- Bone Metastases
- Cancer Stem Cells
- Correlative Science
- Clinical Endpoints
- Development of New Products
- Dietary/Environmental Factors
- Genomics
- Health Disparity*
- Imaging
- Immunology
- Inflammation
- Metabolomics
- Proteomics
- Quality of Life
- Targets (e.g., Androgen Receptor)

*Appropriate disparity research areas include, but are not limited to, race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs. PIs submitting health disparity-based research proposals should have or be part of a team that has experience in prostate cancer research and, if applicable, a connection to, or effectiveness in working with, an affected population or community.

IV. SUBMISSION PROCESS STEP 1: PRE-APPLICATION SUBMISSION

Proposal submission is a two-step process, consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/). This section describes the process for pre-application submission. For proposal submission, see Section V. ***Proposal submission will not be accepted unless a pre-application was previously submitted.*** The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or Organization after submission of the pre-application, please contact the eReceipt helpdesk at help@cdmrp.org or 301-682-5507.

For assistance, please see Help Line Information (Section I).

A. Pre-application Components and Submission

The pre-application for a Laboratory-Clinical Transition Award: Stage I consists of a Letter of Intent (LOI) Narrative and the other components discussed below. This subsection provides a summary of the pre-application submission requirements.

All pre-application components for the PCRP Laboratory-Clinical Transition Award: Stage I mechanism, including the LOI Narrative, must be submitted electronically through the CDMRP eReceipt system by the ***5:00 p.m. Eastern time, April 26, 2007 deadline.*** Material submitted after the pre-application submission deadline, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet this deadline shall result in pre-application rejection and subsequent proposal rejection.

1. **Proposal Information:** PIs must enter the Proposal Information as described in the CDMRP eReceipt system before uploading the LOI Narrative.

2. **Proposal Contacts:** Enter contact information for the PI.

3. **Collaborators and Conflicts of Interest (COI):** To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project including collaborators, consultants, and subawardees. Add all individuals outside of the proposal who may have a conflict of interest in the review of this proposal and choose "COI" from the drop-down list to indicate a conflict of interest. Inclusion of FY07 PCRP Integration Panel (IP) members in any capacity in the proposal, budget, or any supporting document is considered a conflict of interest and will result in administrative withdrawal of the proposal. A list of the FY07 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panel07

4. **LOI Narrative:** The LOI Narrative has a ***one-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The LOI Narrative should be a brief description of the research to be conducted.

5. **Formatting Guidelines and Submission:** The LOI Narrative must be a PDF file, in accordance with the formatting guidelines, and uploaded under the "Required Files" tab of the CDMRP eReceipt system.

6. **PI's Responsibility:** The PI is responsible for uploading the LOI Narrative (one-page limit) as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

The electronic PDF file uploaded in the CDMRP eReceipt system is the official pre-application submission file. After conversion of word processing documents to PDF files and before electronic submission, PIs should review their files to ensure that the pre-application complies with the formatting guidelines.

Once the PI has completed the pre-application submission process, the eReceipt system will generate a pre-application file. The PI should download the pre-application file (in XML format) and attach it to form SF424 in Block 20 (pre-application) as part of the proposal submission through Grants.gov. Do not convert this file. ***After submitting the pre-application, do not delay in submitting the proposal.***

7. **AOR Approval:** The pre-application submission does not require approval by the AOR before submission. Please see Appendix 2 for the definition of an AOR.

B. LOI Narrative Review

The LOI will be administratively reviewed prior to peer review; it will not be reviewed during peer and programmatic reviews.

V. SUBMISSION PROCESS STEP 2: PROPOSAL SUBMISSION

This section describes the process for submission of a proposal, once a pre-application has been submitted. Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

Proposal submission will not be accepted unless a pre-application was previously submitted. The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or Organization after submission of the pre-application, please contact the eReceipt helpdesk at help@cdmrp.org or 301-682-5507.

For complete information regarding forms and submission components, as well as general proposal preparation and submission instructions, please see Appendix 3.

Please note, submission of a proposal requires institutional registration with the Central Contractor Registry (CCR), which requires a Data Universal Number System (DUNS) number, Tax Identification Number (TIN) or Employer Identification Number (EIN), and a Commercial and Government Entity (CAGE) code and must be completed well in advance of Grants.gov registration and proposal submission. Please note that CCR registrations have expirations. Plan accordingly and allow several weeks for these registration processes. Grants.gov will not allow proposals to be submitted unless all of the registration steps have been completed.

A. Proposal Components Summary

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. The package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**
    - Pre-application file downloaded from the CDMRP eReceipt system
2. **Attachments Form**
    - Attachment 1: Project Narrative (25-page limit)
    - Attachment 2: Supporting Documentation
        - References Cited and Acronyms and Symbol Definitions
        - Facilities & Other Resources
        - Description of Existing Equipment
        - Publications and/or Patent Abstracts
        - Letters of Institutional Support
        - Letters of Collaboration (if applicable)
        - Patents and Permissions (if applicable)

    - Intellectual and Material Property Plan (if applicable)
  - Attachment 3: Technical and Public Abstracts
  - Attachment 4: Statement of Work (SOW)
  - Attachment 5: Impact Statement
  - Attachment 6: Federal Agency Financial Plan (if applicable)
3. **Research & Related Senior/Key Person Profile (Expanded Form)**
   - PI Biographical Sketch (four-page limit)
   - PI Current/Pending Support
   - Key Personnel Biographical Sketches (four-page limit each)
   - Key Personnel Current/Pending Support
4. **Research & Related Budget Form**
   - Budget Justification
5. **Research & Related Project/Performance Site Location(s) Form**
6. **R&R Subaward Budget Attachment(s) Form (if applicable)**

Grants.gov will only notify PIs of changes made to this Program Announcement and/or Application Package if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. Please note that if the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement).

B. Review Criteria

1. **Peer Review:** All proposals will be evaluated according to the following criteria. Of these, Lead Agent(s), Research Strategy, and Clinical Impact are the most important.

- **Lead Agent(s)**
  - How the scientific rationale supports the feasibility and development of the lead agent(s) as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning
  - Extent of acknowledgement of and compliance with relevant patents and permissions
- **Research Strategy (preliminary data are required)**
  - Whether the study has the potential of developing a viable lead agent that would be ready for cGMP production
  - 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 requirements for IND submissions
- **Clinical Impact**
  - The potential of the agent to have a major impact on prostate cancer clinical care
  - The magnitude and scope of potential clinical applications
- **Personnel**
  - The appropriateness of the research team's background and expertise with respect to its ability to perform the proposed work. This includes any co-investigators (or collaborators)

    - Appropriateness of the levels of effort for successful development of the lead agent(s)
    - Whether letters of collaboration are provided for any proposed collaborative arrangements (as applicable)
- **Environment**
    - The appropriateness of the scientific environment(s) (as applicable) for the proposed research
    - The adequacy of support as demonstrated by the availability of and accessibility to facilities and resources (including collaborative arrangements)
    - The quality and extent of institutional support
- **Budget**
    - How the budget is appropriate for the proposed research

2. **Programmatic Review:** Criteria used by the IP to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers (scientific and consumer),
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be selected by the IP and recommended for funding to the Commanding General, USAMRMC.

VII. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. ***Failure to adhere to formatting guidelines (Appendix 4) makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection.***

The following will result in administrative rejection of the entire proposal:

- All attached files are not in PDF, except for the pre-application file.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Technical or Public Abstracts are missing.
- Statement of Work is missing.
- Impact Statement is missing.
- Required supporting documentation is missing.
- Biographical sketches are missing.
- Budget justification is missing.
- FY07 PCRP IP members are included in any capacity in the pre-application process, the proposal, budget, and any supporting document. A list of the FY07 PCRP IP members may be found at http://cdmrp.army.mil/pcrp/panel07

For any other sections of the proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

VIII. APPENDICES

APPENDIX 1

ELIGIBILITY INFORMATION

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The US Army Medical Research and Materiel Command (USAMRMC) uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] 25.110.)

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

Eligible Institutions: USAMRMC makes awards to institutions; eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies.

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI): A Department of Defense goal is to allocate funds for the Congressionally Directed Medical Research Programs (CDMRP) peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders 12876, 12900, and 13021. Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Duplicate Submissions: Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

APPENDIX 2

GRANTS.GOV INSTRUCTIONS

A. Public Law 106-107

Proposals requesting funding from the CDMRP will be submitted through the Federal Government's single entry portal, Grants.gov, in compliance with Public Law 106-107 (P.L. 106-107). The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted in November 1999. The purposes of the P.L. 106-107 are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

Individual program announcements and required forms can also be found on this website. As in previous years, award mechanisms requiring pre-applications including Letter of Intent Narrative, preproposals, and/or nominations will be submitted through the CDMRP eReceipt system at https://cdmrp.org.

B. Grants.gov

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between Principal Investigators (PIs) and the Federal agencies that manage grant funds. The grant community, including state, local, and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

In compliance with P.L. 106-107, the USAMRMC requires proposals submitted in response to the program announcement to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual PIs/Project Directors DO NOT register; however, the AOR is required to register. The registration process can take several weeks, so please register as soon as possible.

The following actions are required as part of the registration process. ***The registration process can take several weeks.*** If you do business with the Federal Government on a continuing basis, it is likely you have already completed some of the actions, e.g., obtaining a DUNS number or registration in CCR. Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp

1. Applicant Organization Must Have a Data Universal Number System (DUNS) Number

An organization will need a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B)

(http://fedgov.dnb.com/webform/displayHomePage.do). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/index.jsp). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

2. **Applicant Organization Must be Registered with the Central Contractor Registry (CCR)**

An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates institution information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. ***CCR registrations have an expiration – please verify the status of your organization's CCR registration well in advance of the proposal submission deadline.***

You can register by calling the CCR Assistance Center at 888-227-2423 or register online at http://www.ccr.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization. Allow a minimum of 5 business days to complete the entire CCR registration. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service (IRS).

Foreign organizations must obtain a CAGE code prior to registering with the CCR. A CAGE code can be obtained by calling 269-961-7766 or online at http://www.dlis.dla.mil/Forms/Form_AC135.asp.

3. **Authorized Organizational Representative (AOR) must be registered with Grants.gov**

Before submitting a proposal, an organization representative needs to register to submit on behalf of the organization at Grants.gov - https://apply.grants.gov/OrcRegister. An organization's E-Business point of contact (POC), identified during CCR registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals without permission. The AOR's username and password serve as "electronic signatures" when an application is submitted on Grants.gov. ***Note: In some organizations, a person may serve as both an E-Business POC and an AOR.***

An AOR must first register with the Grants.gov credential provider at https://apply.grants.gov/OrcRegister to obtain a username and password. The AOR must then register with Grants.gov for an account at https://apply.grants.gov/GrantsgovRegister. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

APPENDIX 3

INFORMATION FOR PROPOSAL SUBMISSION

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/). This section describes the process for proposal submission. For pre-application submission, see Section IV. Proposal submission will not be accepted unless a pre-application was previously submitted. This appendix outlines how to prepare a proposal application for submission through Grants.gov.

Each submission must include the completed package of forms identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. The submission of specific documents will depend upon the award mechanism for which this proposal is being submitted, as specified in Section V and described below. All attachments must be uploaded as a PDF file in accordance with the formatting guidelines in Appendix 4 except for the pre-application XML file.

Fill in the ***Application Filing Name*** on the first screen of the Grant Application Package using the CDMRP log number acquired during the pre-application process. ***Do not fill in the Competition ID.***

Click on "Help Mode" (see arrow in Figure 1 below) in the PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in this application package.

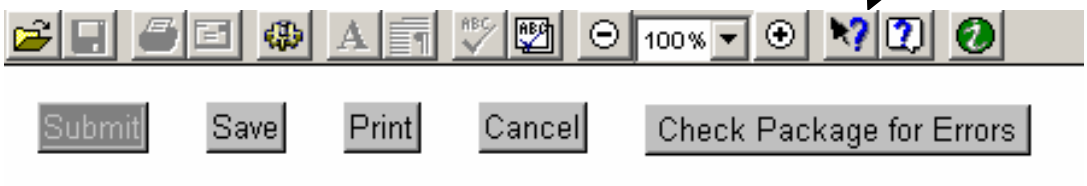

Figure 1: Grants.gov Application PureEdge Toolbar

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	Pre-application XML File	Enter the appropriate information in data fields
Attachments Form	Project Narrative (Narrative.pdf)	Upload as Attachment 1
	Supporting Documentation (Support.pdf)	Upload as Attachment 2
	Technical and Public Abstracts (Abstracts.pdf)	Upload as Attachment 3
	Statement of Work (SOW) (SOW.pdf)	Upload as Attachment 4
	Impact Statement (Impact.pdf)	Upload as Attachment 5
	Federal Agency Financial Plan (if applicable) (FedFin.pdf)	Upload as Attachment 6
Research & Related Senior/Key Person Profile (Expanded) Form	PI Biographical Sketch (Biosketch_LastName.pdf)	Attach to PI Biographical Sketch field
	PI Current/Pending Support (Support_LastName.pdf)	Attach to PI Current & Pending Support field
	Key Personnel Biographical Sketches (Biosketch_LastName.pdf)	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support (Support_LastName.pdf)	Attach to Current & Pending Support field for each senior/key person
Research & Related Budget Form	Budget Justification for entire performance period (Justification.pdf)	Attach to Section K in budget period one
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets and justifications (Justification_LastName.pdf)	Attach a separate budget with justification for each subaward

During award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, regulatory documents related to human and animal studies, and other documents will be requested from the PIs. At that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the AOR.

A. SF-424 (R&R), Application for Federal Assistance Form.

This form is required for each application. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this application package. The form is self-explanatory, with the following exceptions:

- **Applicant Identifier** box should be filled in with the submitting Institution's Control Number.
- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions the "Application" box should be chosen. For substantial changes that must be made after the original submission, the complete application package must be resubmitted. In these cases, the "Changed/Corrected Application" box must be checked and the Grants.gov tracking number must be entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable
- **Block 4 – Federal Identifier Box.** This box will be populated by Grants.gov for an original application, but the Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application) must be manually entered for changed or corrected applications.
- **Block 13 – Proposed Project.** The start date should be 9 months to a year from deadline for proposal submission for this award mechanism.
- **Block 14 – Congressional Districts Of.** If applying from a foreign institution enter "00-000" for both applicant and project.
- **Block 17 – Is Application Subject to Review by State Executive Order 12372 Process?** Choose option, b. NO, program is not covered by E.O.12372.
- **Block 19 – Authorized Representative.** The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. ***Hard copies of applications will not be accepted.***
- **Block 20 – Pre-application** box and attachment should be used to attach the pre-application file associated with this proposal. This pre-application file must be downloaded from the CDMRP eReceipt system. ***Please do not convert this XML file to PDF.***

B. Attachments Form

The following information must be included as attachments to this form in accordance with the formatting guidelines specified in Appendix 4:

Attachment 1: Project Narrative: 25-page limit. The Project Narrative is the main body of the proposal. The Project Narrative must be submitted as a single PDF file named "Narrative.pdf," in accordance with the formatting guidelines specified in Appendix 4.

The preclinical drug development process may require resources beyond those available at a single laboratory. Therefore, the Stage I Award is open to multi-laboratory and/or multi-

institutional collaborations. ***Participating institutions must be willing to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure that the intent of the mechanism is met.***

Describe the proposed project using the outline below. The NCI has constructed developmental pathways for translational research (http://www.cancer.gov/images/trwg/Developmental-Pathway-Agent-Drug_Biologics.pdf) 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. Please be aware that Laboratory-Clinical Transition Award: Stage I only supports research from the identification of a lead agent up to but not including cGMP production of the agent.

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

2. **Lead Agent(s):** Describe the lead agent(s) and their clinical utility. Indicate whether the lead agent or agents are being developed in partnership with another institution and the nature of this partnership.

3. **Objective:** State the objective to be reached.

4. **Specific Aims:** Concisely explain the project's specific aims. If this proposal is part of a larger study, present only DOD-funded tasks.

5. **Research Strategy:** Describe the experimental design for preclinical validation of the lead agent(s) under development. Please see the award description for examples of appropriate research. Describe in detail the methods and analyses, including appropriate controls and a timeline for the completion of each proposed task. Address potential problem areas and present alternative methods and approaches.

The 25-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

Attachment 2: Supporting Documentation. Upload these sections as a single PDF file named "Support.pdf," in accordance with the formatting guidelines specified in Appendix 4.

a. References Cited and Acronyms and Symbol Definitions: No page limit.

- **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.
- **Acronyms and Symbol Definitions:** Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.

b. Facilities & Other Resources: No page limit. Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to the USAMRMC. Indicate if Government-owned facility or equipment is 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.

c. Description of Existing Equipment: No Page Limit. Include a description of existing equipment to be used for the proposed research project.

d. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. A maximum of five publication reprints and/or patent abstracts is allowed; extra items will not be reviewed.

e. Letters of Institutional Support: Provide letter(s) of institutional support, signed by the Department Chair or appropriate institutional official, that reflects the laboratory space, equipment, and other resources available to the PI for this project.

f. Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or institution.

g. Patents and Permissions (if applicable): No page limit. As appropriate, 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 block the development of the lead agent(s). If the project requires the use of a non-commercially available technology/material that is patented by a third party, provide documentation that the third party patent holder does not object to the PI's use.

h. Intellectual and Material Property Plan (if applicable): No page limit. Provide a plan for resolving intellectual and material property issues among participating institutions.

Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.***

Attachment 3: Technical and Public Abstracts. The technical and public abstracts must be submitted as a single PDF file named "Abstracts.pdf," in accordance with the formatting guidelines specified in Appendix 4. Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included in either the technical or the public abstract.

Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed in either abstract.

Technical Abstract: One-page limit. Use the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work.
- **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:** Provide a brief statement explaining the impact of the proposed work to the program goals. Describe how the lead agent to be developed will have an impact on the prevention, detection, or treatment of prostate cancer.

Public Abstract: One-page limit. Start on a new page. The public abstract is an important component of the proposal review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposal in a manner readily understandable by non-scientists.
- 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 consumer-related outcome?

Attachment 4: Statement of Work (SOW): Two-page limit. The SOW must be submitted as a single PDF file named "SOW.pdf," in accordance with the formatting guidelines specified in Appendix 4. The Statement of Work is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's Statement of Work must include aims to be funded by this proposal. The Statement of Work should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the period of performance for the proposed effort;
    - Allow at least 6 months for regulatory review and approval processes for studies involving human subjects;
    - Allow 2 to 4 months for regulatory review and approval processes for animal studies;
- (As applicable) Denote how selection of the lead agent will be completed within 12 months of the award date. If these studies are not completed within 12 months of award initiation, funding for the award will be terminated.

- For animal and human studies (including tissue, anatomical, or biological substances), indicate the sample size projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

Attachment 5: Impact Statement: One-half-page limit. The Impact Statement must be submitted as a single PDF file named "Impact.pdf," in accordance with the formatting guidelines specified in Appendix 4. State explicitly how the proposed work will have an impact on the prevention, detection, or treatment of prostate cancer. Explain the potential clinical applications, benefits, and risks.

The Impact Statement will be available for both peer and programmatic review.

Attachment 6: Federal Agency Financial Plan (if applicable). Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2008, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. The Federal Agency Financial Plan must be submitted as a single PDF file named "FedFin.pdf," in accordance with the formatting guidelines specified in Appendix 4.

C. Research & Related Senior/Key Person Profile (Expanded Form)

Include the requested information for each senior/key person proposed on the project. Each attachment must be a single PDF file, in accordance with the formatting guidelines.

1. **PI Biographical Sketch: Four-page limit.** Suggested format is provided as Form 1. The biosketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the PI.

2. **PI Current/Pending Support: No page limit.** Current/Pending Support for the PI must be submitted as a PDF file in accordance with the formatting guidelines specified in Appendix 4. This file must be named "Support_LastName.pdf," where "LastName" is the last name of the PI.

Proposals submitted under this program announcement should not duplicate other funded research projects.

For all existing and pending research projects involving the PI include:

- Title
- Time commitments
- Supporting agency
- Name and address of the Funding Agency's Procuring Contracting/Grants Officer
- Performance period

- Level of funding
- Brief description of the project's goals
- List of the specific aims.

Provide justification for the requested support and identify where the projects overlap or parallel. If no current support exists, enter "None." Updated current and pending support will be required during award negotiations.

3. **Key Personnel Biographical Sketches: Four-page limit per individual.** Suggested format is provided as Form 1. Each biosketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the appropriate individual.

4. **Key Personnel's Current/Pending Support: No page limit.** Current/Pending Support for each individual must be submitted as a PDF file in accordance with the formatting guidelines specified in Appendix 4. Each file must be named "Support_LastName.pdf," where "LastName" is the last name for the individual. Refer to "PI's Current/Pending Support" above for content of this document, except substituting individual information for that of the PI.

D. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. All costs must be entered in US dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.

The following cost regulations and principles must be adhered to budget calculations:

- **Subcontracting Indirect Costs:** When the applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.
- **Maximum Obligation:** The USAMRMC does not amend grants to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the following regulations and principles:
  - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.
  - **Educational Institutions:** OMB Circular A-21, Cost Principles for Educational Institutions.
  - **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.

- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments.
- **Cost of Preparing Proposals:** The cost of preparing proposals in response to this program announcement is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and OMB Circulars A-21 and A-122.

Section A & B – Senior/Key Person and Other Personnel: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period of performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K).

The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

Section C – Equipment Description: It is DOD policy that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 2 years and an acquisition cost of $5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification (Section K) to include:

- Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
- Historical Cost: Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
- Estimate: Include rationale for estimate and reasons for not soliciting current quotes.
- Special test equipment to be fabricated by the contractor for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.

- Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.
- Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

Section D – Travel

- **Travel costs to attend one scientific/technical meeting per year.** Costs should not exceed $1,800.
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the United States, including between foreign countries, requires prior approval from USAMRAA 90 days before travel.
- **Travel to CDMRP-required meetings** (if applicable) (Section II.C). Costs should be reasonable.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F – Other Direct Costs (as applicable)

Section F.1 – Materials and Supplies (Consumables): The justification (to be included in Section K) supporting material and supply (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

Section F.2 – Publication Costs: This section is self-explanatory.

Section F.3 – Consultant Services: Regardless of whether funds are requested, the justification (to be included in Section K) should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

Section F.4 – ADP/Computer Services: This section is self-explanatory.

Section F.5 – Subaward/Consortium/Contractual Costs: On the project's Research and Related Budget Form, enter the total funds requested for (1) all subaward/consortium organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

Section F.6 – Equipment or Facility Rental/User Fees: This section is self-explanatory.

Section F.7 – Alterations and Renovations: Not allowable.

Sections F.8–F.10 – Research-Related Subject Costs: Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

Sections F.8–F.10 – Other Direct Costs (if applicable): Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified in Section K.

Section G – Direct Costs: This section is self-explanatory. All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

Section H – Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. If negotiated forecast rates do not exist, provide sufficient detail in the budget justification (Section K) regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions. Commercial firms can also visit www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established. When the applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.

As a minimum, justification for indirect costs should identify:

- All individual cost elements included in each forecast rate;
- The basis used to prorate indirect expenses to cost pools, if any;
- How each rate was calculated; and
- The distribution basis of each developed rate.

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

Section J – Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a profit/fee is negotiated, a contract will be awarded. Any fixed fee applied to the research project must be listed and any claimed Facilities Capital Cost of Money supported by **DD Form 1861** (www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html) must be submitted with the proposal.

Section K – Budget Justification: The Budget Justification for the entire performance period must be attached as a PDF file named "Justification.pdf" to the Research & Related Budget – Section K (under budget period one). Organizations must provide sufficient detail

and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.

The budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods.

E. Research & Related Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Please note that each additional research site requesting funds will require a subcontract budget.

F. R&R Subaward Budget Attachment(s) Form (optional form; use if applicable)

Please note that the files to be attached to the R&R Subaward Budget Attachment(s) Form must be PureEdge documents. Extract an R&R Subaward Budget Attachment for each subaward, using the button provided on this form. Save each attachment to your computer and complete the form(s).

The Budget Justification for each subaward must be attached as a PDF file named "Justification_LastName.pdf" (where "LastName is the investigator of the subaward) to the Research & Related Budget – Section K for that subaward. Each subaward budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods for the subaward. Once all subaward budget files are completed, attach all subaward budget file(s) for this application to the R&R Subaward Budget Attachment(s) Form.

The DUNS number for each subaward site should be included on this form.

A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. The following information must be provided on subawards totaling $10,000 or more:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.
- The applicant's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $500,000 and the applicant is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the applicant is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

APPENDIX 4

FORMATTING GUIDELINES

The proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF, except for the pre-application file (XML file) attached to block 20 of SF-424.
- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Proposals may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, Principal Investigators may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are encouraged.
- **Language:** English.
- **Headers and Footers:** Should not be used.
- **Page Numbering:** Should not be used.

All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded as a PDF file.

APPENDIX 5

AWARD ADMINISTRATION INFORMATION

A. Award Notices

Each Principal Investigator (PI) will receive notification of the award status of his or her proposal. A copy of the peer review summary statement, if applicable, will be posted to the Congressionally Directed Medical Research Programs (CDMRP) eReceipt system. PIs can expect to receive this notification approximately 4 weeks after programmatic review.

B. Administrative Requirements

Awards are made to organizations, not individuals. The PI must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and Department of Defense [DOD] Grant and Agreement Regulations) to be eligible for an award. Any organization requesting receipt of an award through this program announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

If allowed, a change in institutional affiliation will require the investigator to resubmit the entire proposal packet through his or her new institution to include any regulatory documentation that may require protocols, etc., to be approved for the new institution. The investigator's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting and regulatory review and a subsequent delay in resuming work on the project.

C. Award Negotiation

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the US Army Medical Research Acquisition Activity (USAMRAA). A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the PI's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

D. Disclosure of Proprietary Information outside the Government

By submitting a proposal, the PI understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The US Army Medical Research and Materiel Command (USAMRMC) will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes

and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

E. Government Obligation

PIs are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. PIs who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

F. Information Service

PIs may use the technical reference facilities of the National Technical Information Service (www.ntis.gov), for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

G. Inquiry Review Panel

PIs may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

H. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

I. J-1 Visa Waiver

It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

APPENDIX 6

REGULATORY REQUIREMENTS AND REVIEWS

The Principal Investigator (PI) may not use, employ, or subcontract for the use of any human subjects, human biological substances, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the US Army Medical Research and Materiel Command (USAMRMC).

Concurrent with the US Army Medical Research Acquisition Activity (USAMRAA) negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form to be submitted upon request. The applicable USAMRMC regulatory office will review documents related to research involving human subjects, human anatomical substance use, and animal use, which should be submitted upon request to ensure that Department of Defense (DOD) regulations are met.

A. Certificate of Environmental Compliance

The Certificate of Environmental Compliance will be requested at award negotiations. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

B. Safety Program Documents

The Principal Investigator Safety Program Assurance form will be requested at award negotiations.

A Facility Safety Plan is required; it will be requested at award negotiations. A Facility Safety Plan from the PI's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/docs/rcq/sohd/Facility_Safety_Plan_Approved_Institutions.pdf. If the PI's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested by the Congressionally Directed Medical Research Programs (CDMRP) if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP; formerly Regulatory Compliance and Quality), must review and approve all animal use

prior to the start of working with animals. PIs must complete and submit the animal use appendix titled "Research Involving Animals", which can be found on the ACURO website https://mrmc-www.army.mil/rodorpaurd.asp). Allow 2 to 4 months for regulatory review and approval processes for animal studies.

Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

D. Research Involving Human Subjects or Biological Substances

Projects involving human subjects or specimens will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b) (4), qualify for expedited review under 32 CFR 219.110 or 21 CFR 56.1102, or involve the use of only commercially available anonymized specimens.

In addition to local Institutional Review Board (IRB) approval or determination of exempt status, a second level of review is required by the DOD for concurrence with the exempt status. This second review is conducted by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO). Documents supporting the exempt status of the project will be requested at a later date. These documents will include documentation of local IRB determination of exempt status and the completed USAMRMC Office of Research Protections Claim of Exemption Form. For studies using only commercially available specimens, the USAMRMC Office of Research Protections Claim of Exemption Form will be requested.

1. **Requirements:** Specific requirements for research involving human subjects or human biological substances can be found at https://mrmc.amedd.army.mil/rodorptoolkit.asp.

   Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

   It is expected that there will be timely resolutions of human subjects protocols submitted to the investigator's local IRB.

   Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.detrick.army.mil/rodorphrpo.asp.

2. **Informed Consent Form:** An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

3. **Intent to Benefit:** Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; http://www.dtic.mil/biosys/downloads/title10.pdf) applicable to DOD-sponsored research before writing a research protocol. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

4. **Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells:** Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g 2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

APPENDIX 7

REPORTING REQUIREMENTS

The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full US Army Medical Research and Materiel Command reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

1. **Research Progress Reports.** Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. Additional reporting may be required as stipulated during award negotiations. Copies of all scientific publications and patent applications resulting from Congressionally Directed Medical Research Programs funding should be included in the progress report. The Government reserves the right to request additional reports.

2. **Fiscal Reports.** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

3. **Non-Exempt Human Studies Reports.** For non-exempt human subjects research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

4. **Animal Use Reports.** Principal Investigators are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

APPENDIX 8

ACRONYM LIST

ACURO.....Animal Care and Use Office
ADP.....Automated Data Processing
AOR .....Authorized Organizational Representative
ASDRP.....Autism Spectrum Disorder Research Program
AVI .....Audio Video Interleave
BCRP .....Breast Cancer Research Program
CCR.....Central Contractor Registration
CDMRP.....Congressionally Directed Medical Research Programs
CFDA.....Catalog of Federal Domestic Assistance
CFR.....Code of Federal Regulations
cGMP .....Current Good Manufacturing Practices
CAGE.....Commercial and Government Entity
COI.....Conflicts of Interest
CMLRP .....Chronic Myelogenous Leukemia Research Program
CR .....Contract Representative
DFARS.....Department of Defense Federal Acquisition Supplement
DOD.....Department of Defense
DODGAR .....Department of Defense Grant and Agreement Regulations
DUNS.....Data Universal Number System
EIN.....Employer Identification Number
EPLS .....Excluded Parties List System
FAR.....Federal Acquisition Regulation
FDA.....Food and Drug Administration
FY .....Fiscal Year
GCP.....Good Clinical Practice
GLP .....Good Laboratory Practice
GWVIRP.....Gulf War Veterans' Illnesses Research Program
HBCU/MI .....Historically Black Colleges and Universities/Minority Institutions
HIPAA .....Health Insurance Portability and Accountability Act
hES.....Human Embryonic Stem
HRPO.....Human Research Protection Office
HSRRB .....Human Subjects Research Review Board
IDE.....Investigational Device Exemption
IND .....Investigational New Drug
IP.....Integration Panel
IRB.....Institutional Review Board
IRS .....Internal Revenue Service
JPEG .....Joint Photographic Experts Group
LAR.....Legally Authorized Representative
LOI.....Letter of Intent
M.....Million
MB .....Megabyte

MPEG .....Moving Picture Experts Group
NIH .....National Institutes of Health
NFRP.....Neurofibromatosis Research Program
OCRP .....Ovarian Cancer Research Program
OMB .....Office of Management and Budget
ORP.....Office of Research Protections
PCRP.....Prostate Cancer Research Program
PDF .....Portable Document Format
PI.....Principal Investigator
P.L. .....Public Law
POC.....Point of Contact
PRMRP .....Peer Reviewed Medical Research Program
R&R OPI.....Research & Related Other Project Information
SOW.....Statement of Work
SPORE .....Specialized Programs of Research Excellence
TIFF .....Tagged Image File Format
TIN.....Tax Identification Number
TSCRP .....Tuberous Sclerosis Complex Research Program
URL.....Uniform Resource Locator
USAMRAA.....US Army Medical Research Acquisition Activity
USAMRMC.....US Army Medical Research and Materiel Command
USC.....United States Code
WAV .....Waveform Audio
XML.....Extensible Markup Language

IX. CDMRP-SPECIFIC FORMS

FORM 1

BIOGRAPHICAL SKETCH

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.