I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Career Development Award

Announcement Type: 1ˢᵗ Modification

Funding Opportunity Number: W81XWH-17-PRCRP-CDA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 20, 2017

- **Application Submission Deadline:** 11:59 p.m. ET, October 4, 2017

- **End of Application Verification Period:** 5:00 p.m. ET, October 10, 2017

- **Peer Review:** November 2017

- **Programmatic Review:** February 2018

This Program Announcement must be read in conjunction with the General Application Instructions version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Peer Reviewed Cancer Research Program (PRCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The PRCRP was initiated in 2009 to provide support for research of exceptional scientific merit and is managed by the CDMRP. Appropriations for the PRCRP from FY09 through FY16 totaled $199.8 million (M). The FY17 appropriation is $60M.

The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on active duty Service members, their families, and the American public. The PRCRP is charged by Congress with the mission to investigate cancer risks and knowledge gaps that may be relevant to active duty Service members, their families, other military beneficiaries, and the American public.

II.A.1. FY17 PRCRP Topic Areas

To be considered for funding, applications for the FY17 PRCRP Career Development Award *must* address at least one of the FY17 PRCRP Topic Areas as directed by Congress. Research applications in the areas of breast, prostate, lung (excluding mesothelioma), kidney, or ovarian cancer will *not* be accepted. The FY17 PRCRP Topic Areas are listed below.

- Bladder cancer
- Brain cancer *(new for FY17)*
- Colorectal cancer
- Immunotherapy[*]
- Listeria-based regimens for cancer
- Liver cancer
- Lymphoma

- Melanoma and other skin cancers
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors
- Stomach cancer
- Cancer in children, adolescents, and young adults[†] *(new for FY17)*

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[*] As derived from the National Cancer Institute Dictionary of Cancer terms (https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=45729). Immunotherapy is a biological therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer.
[†] The definition of adolescents and young adults is derived from the National Cancer Institute (https://www.cancer.gov/types/aya) and can be considered to be people between the ages of 15-39 years.

II.A.2. FY17 PRCRP Military Relevance Focus Areas

In addition to addressing at least one of the required FY17 PRCRP Topic Areas in
Section II.A.1, applications for the PRCRP Career Development Award *must* also address at
least one of the FY17 PRCRP Military Relevance Focus Areas. Military relevance in medical
research focuses on critical health issues or gaps in biomedical knowledge that may affect the
health and well-being of the military.

To address the cancer health needs of both deployed and non-deployed military personnel, their
dependents, retirees, and Veterans, the FY17 PRCRP seeks to support studies that are responsive
to the Military Relevance Focus Areas listed below:

- Militarily relevant risk factors associated with cancer (e.g., ionizing radiation, chemicals,
  infectious agents, and environmental carcinogens)

- Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or
  survivorship that may affect the general population but have a particularly profound impact
  on the health and well-being of active duty Service members, Veterans, and their
  beneficiaries.

For more information on military-related exposures and risk factors for cancer refer to: Military
Relevance Specific to Cancer(s) (http://www.publichealth.va.gov/exposures/health-concerns.asp)
or the PRCRP website: http://cdmrp.army.mil/prcrp/default.

*Investigators are strongly encouraged to collaborate, integrate, and/or align their research
projects with Department of Defense (DoD) and/or Department of Veterans Affairs (VA)
research laboratories and programs.*

II.B. Award Information

The FY17 PRCRP Career Development Award supports independent, early-career investigators
to conduct impactful research with the mentorship of an experienced cancer researcher (i.e., the
Designated Mentor) as an opportunity to obtain the funding, guidance, and experience necessary
for productive, independent careers at the forefront of cancer research. This award supports
impactful research projects with an emphasis on discovery. Under this award mechanism, the
early-career investigator is considered the Principal Investigator (PI), and the application should
focus on the PI's research and career development. It should be clear that the proposed research
is intellectually designed by the PI and not a product of the Designated Mentor. *Preliminary
data are not required. However, logical reasoning and a sound scientific rationale for the
proposed research must be demonstrated.*

Key elements of the Career Development Award mechanism are as follows:

- **Principal Investigator:** The PI must be an independent, early-career researcher or
  physician-scientist within 10 years after completion of his/her terminal degree (excluding
  time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is
  not excluded. The PI's record of accomplishments and the proposed research will be

evaluated regarding his/her potential for contributing to the FY17 PRCRP Topic Area(s) in Section II.A.1. Because career development is the focus of this award, the PI's organization must demonstrate a commitment to the PI through confirmation of laboratory space and a minimum of 30% protected time for the proposed research, though more protected time is highly desirable.

- **Career Development Plan:** A career development plan is required and should be prepared with appropriate guidance from the Designated Mentor. The Designated Mentor must be an experienced cancer researcher as demonstrated by a strong record of funding and publications. In addition, the Designated Mentor must demonstrate a commitment to advancing the PI's career in cancer research. The application should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise to advance an independent career at the forefront of cancer research in at least one of the FY17 PRCRP Topic Area(s) in Section II.A.1.

- **PRCRP Topic Areas:** The proposed research must address at least one of the FY17 PRCRP Topic Areas.

- **Military Relevance:** *The proposed research must address at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2.* The proposed research must be relevant to active duty Service members, Veterans, and their beneficiaries. Military relevance highlights the need to address exposures, conditions, or circumstances that are unique to the military or disproportionately represented within the military beneficiary population. Studies into cancer knowledge gaps that may affect an individual's mission readiness, patient care, and treatment options are critical. Military relevance should be articulated with respect to the overall Military Health System, the VA, and the mission of the DHP. For more information, review the following websites: Military Health System (http://www.health.mil), VA (http://www.va.gov/), the PRCRP (http://cdmrp.army.mil/prcrp/default), and PRCRP Report to Congress (http://cdmrp.army.mil/prcrp/reports/reports).

- **Impact:** The applicant must articulate the potential impact the proposed work will have on cancer research and/or patient care. Impactful research will, if successful, accelerate the movement of promising ideas in cancer research into clinical applications.

The anticipated direct costs budgeted for the entire period of performance for an FY17 PRCRP Career Development Award will not exceed **$360,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or

human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded project will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Clinical trials are not allowed. A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. Applicants with research projects involving a clinical trial may consider applying under the FY17 PRCRP Translational Team Science Award funding opportunity (Funding Opportunity Number: W81XWH-17-PRCRP-TTSA).

Use of Military and VA Populations and/or Resources: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for demonstrating such access. If possible, access to target active duty military and/or VA patient population(s)/resource(s) should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest-ranking person with approval authority, for studies involving active duty military Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research or by advertising to the general public.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 1, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards

are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: A non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

- **Principal Investigator**

  - The PI must be an independent, early-career investigator within 10 years after completion of his/her terminal degree by the time of the application submission deadline (excluding time spent in residency or on family medical leave). Time spent as a postdoctoral fellow is *not* excluded. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.

  - Institutional commitment to the PI's independent career should be demonstrated, including a confirmation of the laboratory space, and *at least 30% of protected time for the proposed research* supported by this award.

- **Designated Mentor**

  - The Designated Mentor must hold a position at or above the level of an Associate Professor (or equivalent).

  - The Designated Mentor must have a proven publication and funding record in cancer research.

The PI and the Designated Mentor do not need to be located at the same organization.

FY17 PRCRP Programmatic Panel members are ineligible to apply and may not be named as a participant on an application.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submitted by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (https://eBRAP.org).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both *pre-application* and *full application* as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.Gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

New for FY17: An invitation to submit a full application package is not required. The pre-application components for the FY17 PRCRP Career Development Award include a Letter of Intent (LOI).

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/).

PIs, mentors, and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application.*" The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY17 PRCRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY17, the

identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Letter of Intent (one-page limit): Provide a brief description of the research to be conducted. Include the FY17 PRCRP Topic Area under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

II.D.2.b. Step 2: Full Application Submission Content

An invitation to submit a full application to the Career Development Award is not required.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-PRCRP-CDA from Grants.gov (http://www.grants.gov).	Download application package components for W81XWH-17-PRCRP-CDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components 　○　Attachments 　○　Research & Related Senior/Key Person Profile (Expanded) 　○　Research & Related Budget 　○　Project/Performance Site Location(s) Form 　○　R&R Subaward Budget Attachment(s) Form (if applicable)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components. 　○　Attachments 　○　Key Personnel 　○　Budget 　○　Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Submit package components to Grants.gov (http://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.

Extramural Submissions	Intramural DoD Submissions
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only –**

    SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications –**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (eight-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Describe the proposed project in detail using the outline below.

    - **Principal Investigator:** Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY17 PRCRP Topic Areas in Section II.A.1, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a cancer researcher and how the proposed training will advance his/her career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

    - **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations and preliminary data that led to the development of the proposed study. Any preliminary data provided should be from the laboratory of the PI, Designated Mentor, or member(s) of the collaborating team.

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

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

    - **Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. 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 cannot be used to conduct clinical trials.***

- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Detail a statistical plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

○ **Attachment 2: Supporting Documentation.** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

- Facilities, Existing Equipment, and Other Resources: 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 award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. 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, confirming the laboratory space, equipment, *support for 30% or more protected time for the PI*, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- – Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual (other than the Designated Mentor) or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- – Intellectual Property: Information can be found in the Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

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

  - ▪ Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- – Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- ○ **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf." The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below.

  - – **Personnel:** Describe the PI's potential for a career at the forefront of cancer research in at least one of the FY17 PRCRP Topic Areas in Section II.A.1. Describe the Designated Mentor's background and experience in cancer research.

  - – **Career Development:** Describe how the award will provide the PI with the opportunity to advance his/her career at the forefront of cancer research.

  - – **Background:** Present the ideas and reasoning behind the proposed project.

  - – **Objective/Hypothesis:** State the hypotheses/study questions and overall objective(s) to be reached.

  - – **Specific Aims:** State the specific aims of this study.

  - – **Study Design:** Briefly describe the study design including appropriate controls.

- **Military Relevance:** Briefly describe how the proposed research is relevant to active duty Service members, Veterans, and other military beneficiaries.

- **Impact:** Summarize the proposed project's potential impact on advancing the current state of cancer research and/or patient care.

○ **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf." The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed research project by including the following elements in plain language.

- Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.

- Describe the PI's career goals in cancer research. How will the award advance the PI's career in at least one of the FY17 PRCRP Topic Areas in Section II.A.1? How does the research and career development plan support the PI in attaining these goals?

- 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? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field. What is the projected time it may take to achieve a clinically relevant outcome? What are the likely contributions of this study to advancing the field of cancer research and/or patient care?

- Describe how the proposed research will benefit active duty Service members, Veterans, and other military beneficiaries.

○ **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Career Development Award mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/ subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory review.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects review (e.g., Investigational New Drug and Investigational Device Exemption) by the U.S. Food and Drug Administration or other Government agency.

- ○ **Attachment 6: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as "MilBen.pdf." *The Relevance to Military Beneficiaries Statement will be evaluated by the FY17 PRCRP Programmatic Panel during programmatic review only.*

    – State the FY17 PRCRP Military Relevance Focus Area(s) in Section II.A.2 to be addressed in the study.

    – Identify the militarily relevant risk factors associated with the FY17 PRCRP Topic Area(s) in Section II.A.1 to be studied and their short- and long-term impact on the basic health, welfare, and/or psychosocial wellness of active duty Service members, Veterans, and other military beneficiaries.

       or

    – Identify the knowledge gap to be studied in the cancer care spectrum (prevention, screening, prognosis, early detection, diagnosis, treatment, and/or survivorship) that may affect mission readiness for active duty military or disproportionately or profoundly affect active duty Service members, Veterans, and other military beneficiaries.

    – Articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the Military Health System for the benefit of active duty Service members, Veterans, and other military beneficiaries.

    – Describe the anticipated short- and/or long-term outcomes of the proposed research and their potential impact on the basic health, welfare, and/or psychosocial wellness of active duty Service members, Veterans, and other military beneficiaries.

    – Describe how the study design will replicate field conditions, if appropriate. If active duty Service members, military families, or Veteran population(s) will be used in the

proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population.

- – If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the Veteran population).

○ **Attachment 7: Impact Statement (one-page limit):** Upload as "Impact.pdf." State explicitly how the proposed work addresses a critical problem in at least one of the FY17 PRCRP Topic Areas in Section II.A.1. Describe the pathway to making an impact on cancer research and/or patient care and explain how the PI's specific research goals, if achieved, would fit into that pathway.

○ **Attachment 8: Career Development Plan (one-page limit):** Upload as "CareerDev.pdf."

- – Clearly describe and outline the individualized career development plan that focuses on at least one of the FY17 PRCRP Topic Areas in Section II.A.1. Highlight the unique features of this career development plan as it pertains specifically to cancer research in the relevant FY17 PRCRP Topic Area(s).

- – Indicate specifically how the individualized career development plan will provide the PI with an opportunity to advance his/her independent career in cancer research.

- – Describe how the career development plan is supported by the research environment and mentorship, including a description of ongoing cancer research at the institution in the relevant FY17 PRCRP Topic Area(s). Include information on collaborations with other investigators.

- – Describe the qualifications of the Designated Mentor including record of research accomplishments, publications, patents, and funding in cancer research. Describe the Designated Mentor's track record for training early-career investigators. If the Designated Mentor and PI are located at different organizations, describe how appropriate direction and oversight will be accomplished.

○ **Attachment 9: PI's Eligibility Statement (one-page limit):** Upload as "PIEligibility.pdf." Use the Eligibility Statement template (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.

○ **Attachment 10: Letter from Designated Mentor (two-page limit):** Upload as "MentorLetter.pdf." Provide a signed letter from the Designated Mentor indicating recommendation, support, and planned interactions with the PI for the proposed work. The letter from the Designated Mentor should detail individualized interaction between the Designated Mentor and the PI for further career development. Include information on the Designated Mentor's record of preparing early-career investigators for careers in cancer research.

○ **Attachment 11: Letters Confirming Access to Target Military or VA Patient Population(s) or Resources (e.g., Human/Animal Anatomical Substances, Databases),** *if applicable* **(one-page limit per letter):** Upload as "Access.pdf." If the proposed research plan involves access to active duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

○ **Attachment 12: Use of Hazardous Chemical or Biological Agents,** *if applicable* **(no page limit):** Upload as "Hazardous.pdf." The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information, such as Centers for Disease Control and Prevention registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from Government sites issuing any agent(s). Indicate if agents used are purchased commercially, and, if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

○ **Attachment 13: DoD Military Budget Form(s),** *if applicable***:** Upload as "MFBudget.pdf." If a Military Facility (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3 and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2 for detailed information.

  ○ PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.

  ○ PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- ○ Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."

  Include Designated Mentor's (and co-mentor's, if applicable) biographical sketch.

- ○ Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

  Include Designated Mentor's (and co-mentor's, if applicable) previous/current/pending support.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5 and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

  R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

  - ○ **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

  - ○ **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 13. (Refer to the General Application Instructions, Section IV.A.7. for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete

the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in <u>Section I, Overview of the Funding Opportunity</u>. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **$360,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$360,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary

- Research supplies

- Clinical research costs (*funding for clinical trials is not permitted*)

- Travel between collaborating organizations

- Travel costs for up to one investigator to travel to two scientific/technical meetings per year

Must not be requested for:

- Clinical trial costs

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.4, for budget regulations and instructions for the Research & Related Budget. *For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4.*

The CDMRP expects to allot approximately $13.25M of the $60M FY17 PRCRP appropriation to fund approximately 23 Career Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Principal Investigator**

  ○ Whether the PI meets the eligibility requirements.

  ○ To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research.

- To what extent the PI's record of accomplishments and letters of support demonstrate his/her potential for advancement as a productive, independent investigator in cancer research in at least one of the FY17 PRCRP Topic Areas in Section II.A.1.

- **Career Development Plan and Environment**

  - How well the PI has outlined a detailed, individualized career development plan that will effectively advance his/her independent career as a cancer researcher in at least one of the FY17 PRCRP Topic Areas in Section II.A.1.

  - To what degree the proposed development plan is appropriate and will prepare the PI for a successful independent career at the forefront of cancer research.

  - Appropriateness of the levels of effort by the PI, Designated Mentor, and other key personnel to ensure the success of this research effort.

  - To what extent unique features of the research environment are integrated into the career development plan, including potential collaborations, and how appropriate the features are to advance the independent career of the PI.

  - Whether there is a clear organizational commitment for laboratory space and protection of at least 30% of the PI's time for the proposed research.

  - How well the research requirements are supported by the availability and accessibility to facilities and resources (including collaborative arrangements).

  - Whether the Designated Mentor (and co-mentor, if applicable) is an independent, established researcher in cancer research as demonstrated by a record of publications, patents, and/or funding history.

  - To what degree the Designated Mentor's commitment demonstrates an individualized plan for interaction between the Designated Mentor and the PI for further career development.

  - To what degree the Designated Mentor's track record in mentoring early-career investigators indicates the potential for successful mentorship and advancement of the PI's independent research career.

- **Research Strategy and Feasibility**

  - How well the proposed research addresses an important clinical and/or translational question relevant to at least one of the FY17 PRCRP Topic Areas in Section II.A.1.

  - How well the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if included), and logical reasoning.

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.

- To what degree the research project is appropriate for advancing the PI's independent career at the forefront of cancer research and/or patient care.

- How well the PI acknowledges potential problems and address alternative approaches.

- Whether the applicants demonstrate the availability of tissue, data, or human subjects, if applicable.

- If applicable, to what degree the intellectual and material property plan is appropriate.

- To what degree the statistical plan is appropriate for the experimental methodology being used.

- If applicable, whether the power analysis for the proposed study adequately represents an assessment of the population or subpopulation proposed.

- **Impact**

  - How well the proposed research addresses a critical problem and/or patient care in at least one of the FY17 PRCRP Topic Areas in Section II.A.1.

  - To what degree the proposed research goals, if achieved, will contribute to advancing the field of cancer research and/or patient care in at least one of the FY17 PRCRP Topic Areas.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Budget**

  - Whether the maximum **direct** costs are equal to or less than the allowable maximum direct costs as published in the Program Announcement.

  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement.

  - Whether there may be significant overlap with existing or pending awards of the PI.

- **Application Presentation**

  - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers

- Relevance to the mission of the DHP and FY17 PRCRP, as evidenced by the following:

   ○ Adherence to the intent of the award mechanism

   ○ Program portfolio composition

   ○ Military relevance

   ○ Relative Impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PRCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at his/her option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about him/herself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the

research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. Award Transfers

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the [USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#) and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. Annual progress reports as well as a final progress report will be required.

In addition to written progress reports, annual Award Charts will be required. For the Career Development Award mechanism, use the format example titled "Generic Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

> Phone: 301-682-5507

> Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516b. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY17 PRCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including,

but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY17 PRCRP Programmatic Panel members can be found at http://cdmrp.army.mil/prcrp/panels/panels17.***

- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

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

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural DoD organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds as subawards or contracts to extramural collaborators.

- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

- If a clinical trial is proposed, the application will be withdrawn.

- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

- If the application does not address at least one of the FY17 PRCRP Topic Areas in Section II.A.1, the application will be withdrawn.

- If the application does not address at least one of the FY17 PRCRP Military Relevance Focus Areas in Section II.A.2, the application will be withdrawn.

- If the application proposes breast, prostate, lung (excluding mesothelioma), kidney, or ovarian cancer research, the application will be withdrawn.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Relevance to Military Beneficiaries Statement: Upload as Attachment 6 with the file name "MilBen.pdf."	
	Impact Statement: Upload as Attachment 7 with the file name "Impact.pdf."	
	Career Development Plan: Upload as Attachment 8 with the file name "CareerDev.pdf."	
	PI's Eligibility Statement: Upload as Attachment 9 with the file name "PIEligibility.pdf."	
	Letter from Designated Mentor: Upload as Attachment 10 with the file name "MentorLetter.pdf."	
	Letters Confirming Access to Target Military or VA Patient Population(s) or Resources: Upload as Attachment 11 with the file name "Access.pdf," if applicable.	
	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 12 with the file name "Hazardous.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf," if applicable.	

Application Components	Action	Completed
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/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 Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget **(Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Budget **(Intramural submissions only)**	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

ACURO   Animal Care and Use Review Office
ARRIVE   Animal Research: Reporting *In Vivo* Experiments
CDMRP   Congressionally Directed Medical Research Programs
CFR   Code of Federal Regulations
COI   Conflict of Interest
DHA   Defense Health Agency
DHP   Defense Health Program
DoD   Department of Defense
DoDGAR   Department of Defense Grant and Agreement Regulations
DUNS   Data Universal Numbering System
eBRAP   electronic Biomedical Research Application Portal
EC   Ethics Committee
ET   Eastern Time
FAD   Funding Authorization Document
FAPIIS   Federal Awardee Performance and Integrity Information System
FY   Fiscal Year
HRPO   Human Research Protection Office
IACUC   Institutional Animal Care and Use Committee
IRB   Institutional Review Board
LOI   Letter of Intent
M   Million
MIPR   Military Interdepartmental Purchase Request
OASD(HA)   Office of the Assistant Secretary of Defense for Health Affairs
ORCID   Open Researcher and Contributor ID, Inc.
ORP   Office of Research Protections
PI   Principal Investigator
PRCRP   Peer Reviewed Cancer Research Program
RDT&E   Research, Development, Test, and Evaluation
RM   Resource Manager
SAM   System for Award Management
SOW   Statement of Work
USAMRAA   U.S. Army Medical Research Acquisition Activity
USAMRMC   U.S. Army Medical Research and Materiel Command
USC   United States Code
VA   Department of Veterans Affairs