

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

Horizon Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-PRCRP-HA

**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), August 21, 2019
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, September 11, 2019
- **Application Submission Deadline:** 11:59 p.m. ET, September 11, 2019
- **End of Application Verification Period:** 5:00 p.m. ET, September 16, 2019
- **Peer Review:** November 2019
- **Programmatic Review:** January 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190218. The General Application 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 2019 (FY19) 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 for the benefit of Service members, their families, and the American public. Appropriations for the PRCRP from FY09 through FY18 totaled \$339.8 million (M). The FY19 appropriation is \$90M.

The goal of the PRCRP is to increase mission readiness and quality of life by decreasing the burden of cancer on 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. FY19 PRCRP Topic Areas

To be considered for funding, applications for the FY19 PRCRP Horizon Award *must* address at least one of the FY19 PRCRP Topic Areas as directed by Congress. Research applications in the areas of breast, prostate, lung (excluding mesothelioma), kidney, melanoma, or ovarian cancer will *not* be accepted. The FY19 PRCRP Topic Areas are listed below.

- Bladder cancer
- Blood cancers
- Brain cancer
- Cancer in children, adolescents, and young adults¹
- Colorectal cancer
- Immunotherapy²
- Listeria vaccine for cancer
- Liver cancer
- Lymphoma
- Mesothelioma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors
- Rare cancers³
- Stomach cancer

¹ The definition of adolescents and young adults is derived from the National Cancer Institute (NCI) (<https://www.cancer.gov/types/aya>). Research should be targeted toward children (ages 0-14 years), adolescents (ages 15-24 years), and/or young adults (ages 25-39 years).

² As derived from the *NCI 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.

³ Rare cancer is defined by the NCI as a cancer that occurs in fewer than 15 out of 100,000 people each year (<http://www.cancer.gov/publications/dictionaries/cancer-terms/def/791790>).

New for FY19: Studies involving melanoma (including rare subtypes of melanoma) should apply to the new FY19 Melanoma Research Program. Studies involving other skin cancers will be accepted by the PRCRP under an appropriate FY19 PRCRP Topic Area (i.e., immunotherapy).

II.A.2. FY19 PRCRP Military Health Focus Areas

In addition to addressing at least one of the required FY19 PRCRP Topic Areas, applications for the PRCRP Horizon Award ***must*** also address at least one of the FY19 PRCRP Military Health Focus Areas. Relevance to military health in medical research focuses on critical issues or gaps in biomedical knowledge that may affect the health and well-being of the military and their beneficiaries.

It is central to the vision and mission of the PRCRP that applications address how the proposed research is related to military health, mission readiness, and the cancer health needs of both deployed and non-deployed military personnel, their dependents, Veterans, and other military beneficiaries (i.e., family members of retirees). The FY19 PRCRP requires all applications answer at least one of the Military Health Focus Areas listed below:

- ***Environmental/exposure risk factors associated with cancer***
- ***Gaps in cancer prevention, early detection/diagnosis, prognosis, treatment, and/or survivorship that may impact mission readiness and the health and well-being of military members, Veterans, their beneficiaries, and the general public***

Environmental risk factors should be relevant to the activities specific to the military such as deployments that may lead to exposures to potential carcinogens (ionizing radiation, chemicals, infectious agents, etc.). For more information on military-related exposures and risk factors for cancer, applicants should refer to Exposure Related Health Concerns at <https://www.publichealth.va.gov/exposures/health-concerns.asp> or to the PRCRP website (<https://cdmrp.army.mil/prcrp/default>).

Examples of impact on mission readiness may include but are not limited to: improvements in survival while minimizing late effects that would allow an active duty Service member to return to full duty; treatments that minimize a cancer patient's (either Service member or their family member) time in the hospital thus maximizing the time the Service member is on duty; minimizing cancer relapse for Service members or their families (in the event of a family member's relapse the active duty Service member is called home regardless of deployment status); and improvements in cancer detection that would lead to the earlier diagnosis thus allowing for improved treatment of the Service member and early return to duty. More information on mission readiness can be found at <https://cdmrp.army.mil/prcrp/pbks/prcrppbk2017.pdf>.

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 FY19 PRCRP Horizon Award supports junior-level scientists in conducting impactful research with the mentorship of an experienced cancer researcher (i.e., Mentor). The intent of the Horizon Award is to recruit junior-level scientists to perform research in one of the FY19 PRCRP Topic Areas. The Horizon Award challenges junior scientists to develop and implement research in the cancer field. This opportunity allows for junior investigators to develop a research project, investigate a problem or question in the field of cancer, and further their intellectual development as a cancer researcher of the future. Under this award mechanism, the junior 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 with assistance from the Mentor. ***Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated. Clinical trials will not be supported by this mechanism.***

Key elements of the Horizon Award are as follows:

- **Principal Investigator:** Both predoctoral candidates and postdoctoral fellows are eligible according to the following definitions:
 - A predoctoral candidate within 2 years of completing required graduate coursework, having completed all laboratory rotations, successfully passed qualifying examinations (excluding time in residency, clinical training, or on family medical leave), and is working in his/her Mentor's laboratory by the time of the application submission deadline.

or

 - A postdoctoral fellow within 3 years of completion of his/her terminal degree (excluding time in residency, clinical training, or on family medical leave) and working in the Mentor's laboratory at the time of the application submission deadline. The PI's record of accomplishments (including but not limited to publications, awards, and research recognition) will be evaluated to determine his/her potential for contributing to the FY19 PRCRP Topic Area(s) the proposed research addresses.
- **Mentor:** The Mentor must be an experienced cancer researcher as demonstrated by a strong record of active funding and publications. In addition, the Mentor must demonstrate a commitment to advancing the PI's career in cancer research. The Mentor's record of accomplishments (such as publications, patents, presentations, etc.) should include documentation of significant contribution to cancer research. If the Mentor is not a researcher in the selected FY19 PRCRP Topic Area of the PI, it is strongly recommended that a collaborator or co-Mentor be named.
- **PRCRP Topic Areas:** The proposed research must address at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).

- **Research Approach:** The scientific rationale and experimental methodology should demonstrate in-depth analysis of the research problem presented. The feasibility of the research design and methods should be well-defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved.
- **Researcher Development Plan:** A researcher development plan is required and should be prepared with appropriate guidance from the Mentor. The application should include a clearly articulated strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed cancer research in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#). ***A commitment of 100% effort by the PI is required for the proposed research.*** If the PI is a predoctoral candidate, the proposed research should be in the topic of the PI's thesis.
- **Impact:** The proposed research should have the potential for significant impact on at least one of the FY19 PRCRP Military Health Focus Areas in one of the FY19 PRCRP Topic Areas.

A Congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY19 PRCRP priorities.

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

The anticipated direct costs budgeted for the entire period of performance for an FY19 PRCRP Horizon Award will not exceed **\$150,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

The CDMRP expects to allot approximately \$3.6M to fund approximately 15 Horizon Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

Awards will be made no later than September 30, 2020. For additional information refer to [Section II.F.1, Federal Award Notices](#).

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 the DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

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) and the award will identify the specific substantial involvement. 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.

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.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. 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 as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of Work \(SOW\)](#). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. 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.

New FY19 definition: A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PI (PI)s/co-PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. 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). Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information.

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 the General Application Instructions, Appendix 1, for additional information.

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.

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: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, other Federal Government organization other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

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

II.C.1.b. Principal Investigator and Mentor

- **The PI must be either:**
 - A predoctoral candidate within 2 years (excluding time in residency, clinical training, or on family medical leave) of completing required coursework, all laboratory rotations, successfully passing qualifying examinations, and is working in his/her Mentor's laboratory by the time of the application submission deadline
 - or*
 - A postdoctoral fellow within 3 years (excluding time in medical residency, clinical training, or family medical leave) of completion of his/her terminal degree, and working in the Mentor's laboratory at the time of the application submission deadline.
 - Each investigator may be named on only one FY19 PRCRP Horizon Award application as the PI.

- **Mentor**

- Must hold a position at or above the level of an Assistant Professor (or equivalent).
- Must have a proven publication and active funding record in cancer research.

The PI and the Mentor must be at the same organization.

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 <https://orcid.org/>.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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.

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 offered by the FY19 PRCRP is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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.

Extramural Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted 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/>).

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

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. 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. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in [Section II.C.1, Eligible Applicants](#).

Intramural DoD Organization Submissions: 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.

For Both Extramural and Intramural Applicants: eBRAP allows 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 full 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 submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required 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 will delay 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 to request a change in designation.

All pre-application components must be submitted through eBRAP (<https://eBRAP.org/>).

The applicant organization and associated PIs and Mentor(s) 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.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

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**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 Research & Related 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 Research & Related 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 applicants 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.

[FY19 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.

- **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).

- **Tab 5 – Pre-Application Files**

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY19 PRCRP Topic Area(s) 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.
- **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals who will provide letters of recommendation. The three letters of recommendation must include one from the Mentor and two (a co-Mentor, if one is named) from other independent researchers with scientific knowledge of and interaction with the PI. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.

- **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

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 (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines. For the Horizon Award, additional application components are also required and should be submitted as directed in the [Additional Application Components](#) section.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. 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-19-PRCRP-HA from Grants.gov (https://www.grants.gov/) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-19-PRCRP-HA from eBRAP (https://ebrap.org/).
Full Application Package Components	
SF424 Research & Related 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.

Extramural Submissions	Intramural DoD Submissions
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable) • Additional Application Component(s) 	<p>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:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites • Other <p>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.</p>
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: 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.</p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>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 next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.</p>

Extramural Submissions	Intramural DoD Submissions
<u>Application Verification Period</u>	
<p>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 may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>.</p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive 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 may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form</i>. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget form 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. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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 Research & Related 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 have 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 (four-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 FY19 PRCRP Topic Areas in [Section II.A.1](#), including qualifications and achievements that make the PI an ideal candidate for this award with respect to the current academic level of the PI (predoctoral candidate or postdoctoral fellow). Describe the PI’s career goals as a cancer researcher. If the PI is a postdoctoral fellow, describe the record of accomplishments (including but not limited to awards, publications, etc.) that may demonstrate how the PI will succeed in a future career in cancer research.
- **Mentor:** Describe the qualifications of the Mentor including record of accomplishments, publications, patents, and funding in cancer research. Describe the Mentor’s track record for training junior investigators. If a co-Mentor is named, describe the co-Mentor’s record of accomplishment, publications, patents, and funding in cancer research, etc.

- **Research:**
 - **Background:** Present the scientific rationale based on literature review for the objective or hypothesis. Describe the experimental methodology and demonstrate an in-depth analysis of the research problem to be studied. Preliminary data are not required. Describe the resources available for the proposed research.
 - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached. The study should be hypothesis-driven.
 - **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 evaluation. Address potential problem areas and pitfalls, and present alternative methods and approaches. A statistical analysis of the proposed research should be included, if applicable, as well as a power analysis to support the design and sample size.
- **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.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 articles 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, 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 or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- Transcripts: Include a copy of the PI’s transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the “Full Announcement” page in Grants.gov) in place of the transcript.
- Intellectual Property: Information can be found in 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.

- **Use of DoD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **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 FY19 PRCRP Topic Areas. Describe the Mentor’s background and experience in cancer research.
- **Researcher Development:** Describe the strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed cancer research in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).
- **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.
 - **Impact:** Summarize the proposed project’s potential impact on advancing the current state of cancer research. Briefly describe how the proposed research is relevant to the health and welfare of active duty Service members, their families, Veterans, and other military beneficiaries.
- **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 PI’s career goals in cancer research.
 - How will the award advance the PI’s career in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#)?
 - How does the researcher development plan support the PI in attaining these goals?
- 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 ultimate applicability of the research. If the research is basic, describe the long-term goals related to patient care, outcomes, or survivorship. Basic research should be framed around the goal of the betterment of the cancer patient or family, etc.
 - 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, their families, Veterans, and other military beneficiaries.
- **Attachment 5: Statement of Work (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 Horizon 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 requirements.
 - 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 applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.
- **Attachment 6: Researcher Development Plan (one-page limit): Upload as “ResearchDev.pdf”.**
- Clearly describe and outline the individualized researcher development plan that focuses on at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#). Highlight the unique features of this researcher development plan as it pertains specifically to cancer research in the relevant FY19 PRCRP Topic Area(s).
 - Clearly articulate a strategy for acquiring the necessary skills, competence, and expertise to successfully complete the proposed cancer research in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).
 - Indicate how the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of cancer, and further intellectual development of the PI as a cancer researcher of the future.
 - Describe the Mentor-PI interaction. Detail how appropriate direction and oversight will be accomplished, including scheduled meetings, committee meetings, and training opportunities. Do not reference or include members of the [FY19 PRCRP Programmatic Panel](#).
 - Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing cancer research at the institution in the relevant FY19 PRCRP Topic Area(s) in [Section II.A.1](#). Include information on collaborations with other investigators, seminars, workshops, and other opportunities to interact with leaders in the cancer field. Do not reference or include members of the [FY19 PRCRP Programmatic Panel](#).

- **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 FY19 PRCRP Topic Areas in [Section II.A.1](#). Describe the pathway to making an impact on cancer research and explain how the PI’s specific research goals, if achieved, would fit into that pathway. The relevance of all research including basic should relate to the outcomes of how it benefits those affected by cancer. *The Impact Statement should be written in plain language for lay persons.*
- **Attachment 8: 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 9: Relevance to Military Health Statement (one-page limit): Upload as “MilHealth.pdf”.** *The Relevance to Military Health Statement will be evaluated by the FY19 PRCRP Programmatic Panel during programmatic review only.*
 - State the FY19 PRCRP Military Health Focus Area(s) in [Section II.A.2](#) to be addressed in the study.
 - Identify the militarily relevant risk factors associated with the FY19 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, early detection, diagnosis, prognosis, 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.
 - 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.
- **Attachment 10: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 11: DoD Military Budget Form(s), if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical 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**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: 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.

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

- 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 uneditable PDF format.
- 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 Mentor’s biographical sketch.
 - Include co-Mentor’s biographical sketch (if applicable).
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - Include Mentor’s previous/current/pending support.
 - Include co-Mentor’s previous/current/pending support (if applicable).

Research & Related Budget: 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.

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.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget form under subaward costs.

Additional Application Components
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In addition to the complete application package, Horizon Award applications also require the following components:

- **Three Confidential Letters of Recommendations (two pages per letter):**

The three letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the [Confidential Letters of Recommendation Submission](#) deadline of September 18, 2019. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Confidential letter(s) of recommendation from the Mentor:** The PI’s Mentor must submit a letter describing the Mentor’s commitment to the PI’s researcher development and mentorship. The Mentor’s letter of recommendation should describe:
 - The PI’s potential to become a successful and independent researcher in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#). The relevance of the proposed research project to the PI’s development as a researcher in at least one of the FY19 PRCRP Topic Areas.
 - The Mentor’s commitment to the career development and mentorship of the PI, including details of his/her proposed interactions with the PI, and how he/she intends to support the PI’s research endeavors.
 - The past experience as a mentor for other predoctoral candidates or postdoctoral fellows with details on the success of the previous mentee(s).
- **Additional confidential letter(s) of recommendation:** The remaining letter(s) should be from (an) independent researcher(s) with scientific knowledge of and interaction with the PI. If a co-Mentor is named, then one of the two additional recommendation letters should be from the co-Mentor, for a total of three letters of recommendation. The letters should highlight the PI’s potential for success in pursuing a career in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#). Specifically, each letter should include the writer’s perspective on:
 - The PI’s qualifications, characteristics, and achievements;
 - The PI’s potential for productivity and desire for establishing a successful career at the forefront of cancer research;
 - The relevance of the proposed research project to the PI’s development as a researcher in at least one of the FY19 PRCRP Topic Areas;
 - The suitability of the Mentor and researcher development plan for providing the PI with a solid foundation in cancer research.

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

Applicant organizations and all sub-recipient 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 organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at 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 [Section I, Overview of the Funding Opportunity](#). 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

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.

Extramural Submission: 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.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI(s) will receive email notification of the 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. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

The maximum period of performance is **2** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$150,000**. 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 **\$150,000** 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 2 years.

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

- PI salary or stipend
- Research supplies
- Workshop costs
- Clinical research costs (*funding for a clinical trial is not allowed*)
- Travel costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to this scientific/technical meeting is to present project outcomes or disseminate project results and/or attend a workshop as designated in the researcher development plan from the FY19 PRCRP Horizon Award.

Must not be requested for:

- Clinical trial costs
- Mentor or co-Mentor salary
- Any other salary other than PI salary

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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 funds 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.5, 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.5.***

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this FY19 funding opportunity will be funded with FY19 funds, which will expire for use on September 30, 2025.

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 one of the eligibility requirements as a predoctoral candidate or a postdoctoral fellow.
 - Whether the PI will commit 100% effort on the proposed research.
 - To what degree the PI's qualifications and achievements demonstrate the PI's potential for a career at the forefront of cancer research in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1.](#)
 - Whether the PI's career goals show a strong personal commitment to advancement toward an independent career in cancer research.
 - Whether the letters of recommendation show the qualifications of the PI to succeed in a career in cancer research.
- **Mentor**
 - Whether the Mentor meets the eligibility requirements.
 - To what degree the Mentor's record of research accomplishments, publications, patents, and funding demonstrate a strong commitment and high level of qualifications in cancer research.
 - Whether the Mentor has successfully trained junior investigators in cancer research.
 - *If applicable*, whether the co-Mentor meets the eligibility requirements of a Mentor.
 - *If applicable*, whether the co-Mentor has a record of research accomplishments (publications, patents, funding) in the FY19 PRCRP Topic Area to demonstrate knowledge in the cancer area being studied.

- **Research**

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data (if included), and logical reasoning.
- Whether the experimental design and the statistical plan, if applicable, are appropriate for the research proposed.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- To what degree the research project is appropriate for the PI's career development as a predoctoral candidate or postdoctoral fellow.
- How well the application acknowledges potential problems and addresses alternative approaches.

- **Researcher Development Plan and Environment**

- Whether the application describes the individualized researcher development plan as focused on one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).
- Whether the researcher development plan articulates a strategy for the PI to acquire the necessary skills, competence, and expertise to successfully complete the proposed cancer research in at least one of the FY19 PRCRP Topic Areas.
- How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of cancer, and further the PI's intellectual development as a cancer researcher of the future.
- To what extent the researcher development plan is supported by the environment and mentorship, including a description of ongoing cancer research in the relevant FY19 PRCRP Topic Area(s) at the institution.
- To what extent unique features of the research environment are integrated into the researcher development plan.
- To what extent the proposed interactions of the PI with the Mentor and other key personnel are appropriate.

- **Impact**

- If the research is basic, how the study addresses the ultimate goal of benefitting those affected by cancer.

- To what degree the proposed research goals, if achieved, will contribute to advancing the field of cancer research in at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).
- To what degree the short- or long-term impact of the proposed research is described.

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

- **Budget**

- Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.
- Whether the budget is appropriate for the proposed research.
- Whether there may be significant overlap with existing or pending awards of the PI or Mentor(s).

- **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 FY19 PRCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - Relevance to the FY19 PRCRP Military Health Focus Areas
 - 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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding

General, USAMRMC, on behalf of the DHA and the OASD(HA). *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 <https://cdmrp.army.mil/about/2tierRevProcess>. A PI Information Paper describing the funding recommendations and review process for the award mechanisms for the PRCRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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, as defined in 2 CFR 200.88, 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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 (DoDGARs), 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 supported with FY19 funds are anticipated to be made no later than September 30, 2020. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from 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 document.**

Federal Government Organizations: Funding made 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through 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. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. 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 DoDGARs found in 32 CFR, Chapter I, 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 latest [DoD R&D General Terms and Conditions](#), the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#): Addendum to the DoD R&D General Terms and Conditions 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. *If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.*

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 Horizon Award mechanism, use the format example “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 Representations (see General Application Instructions, Appendix 5, Section B).

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 20190218b. The Program Announcement numeric version code will match the General Applications Instructions version code 20190218.

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 pre-application or application:

- An FY19 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 FY19 PRCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/prcrp/panels/panels19>.*
- The application fails to conform to this Program Announcement description.
- 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 FY19, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP.
- Applications submitted by an intramural DoD organization if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year (FY19 PRCRP).
- A clinical trial is proposed.
- The named PI does not meet the eligibility criteria.
- The proposed Mentor does not meet the eligibility criteria.
- The application does not address at least one of the FY19 PRCRP Topic Areas in [Section II.A.1](#).

- The application does not address at least one of the FY19 PRCRP Military Health Focus Areas in [Section II.A.2](#).
- The PI is named on more than one FY19 PRCRP Horizon Award application. The first application received will be accepted; any other(s) will be withdrawn.
- The application proposes breast, prostate, lung (excluding mesothelioma), kidney, melanoma, or ovarian cancer research.
- The applicant cannot demonstrate access to the relevant study population or resources.

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 Research & Related Application for Federal Assistance (Extramural submissions only)	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) (Intramural submissions only)	Complete 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"	
	Researcher Development Plan: Upload as Attachment 6 with file name "ResearchDev.pdf"	
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"	
	PI's Eligibility Statement: Upload as Attachment 8 with file name "PIEligibility.pdf"	
	Relevance to Military Health Statement (one-page limit): Upload as Attachment 9 with file name "MilHealth.pdf"	
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	

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	
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed	
Additional Application Components	Action	Completed
Confidential Letters of Recommendation	Confirm upload to eBRAP	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
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
DoDGARs	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
FAQs	Frequently Asked Questions
FSD	Federal Service Desk
FY	Fiscal Year
GSA	General Services Administration
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
NPC	Non-Profit Corporation
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
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, or Mathematics
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