I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Kidney Cancer Research Program

Clinical Consortium Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-19-KCRP-CCA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 17, 2019

- **Application Submission Deadline:** 11:59 p.m. ET, October 1, 2019

- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2019

- **Peer Review:** December 2019

- **Programmatic Review:** February 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) Kidney Cancer Research Program (KCRP) 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 KCRP was initiated in 2017 to provide support for research of exceptional scientific merit in the area of kidney cancer. Appropriations for the KCRP from FY17 through FY18 totaled $25 million (M). The FY19 appropriation is $20M.

The KCRP's vision is to eliminate kidney cancer through collaboration and discovery. The KCRP's mission is to promote rigorous, innovative, high-impact research in kidney cancer for the benefit of Service members, Veterans, and the American public.

II.A.1. KCRP Strategic Plan

The KCRP has prepared a brief synopsis, the KCRP Strategic Plan, which describes KCRP's background and overview, the research funding environment, and strategic direction for the program. Applicants are strongly urged to read and consider the KCRP Strategic Plan before preparing their applications. The KCRP Strategic Plan may be found at **https://cdmrp.army.mil/kcrp/pdfs/KCRP%20Strategic%20Plan.pdf**.

II.A.2. Award History

The KCRP Clinical Consortium Award (CCA) mechanism is being offered for the first time in FY19 and is intended to meet the KCRP's objective of establishing a multi-institutional effort to expedite clinical trials of promising therapeutics for kidney cancer patients.

This funding opportunity will not support research or development of clinical protocols.

II.B. Award Information

The KCRP Clinical Consortium Award is intended to support a major goal, a consortium of exceptional institutions and leading investigators to advance high-impact, novel therapeutic strategies and interventions to improve patient outcomes and significantly decrease the impact of the disease (the "Consortium"). The objectives of the Consortium shall be to design, develop, and conduct Phase I or Phase II-linked Phase I (Phase I/II) clinical trials of promising therapeutic agents for the prevention, detection/diagnosis, management, or treatment of kidney cancer. The KCRP Clinical Consortium Award provides the support to develop and enhance collaborations and resources necessary for a network of organizations to rapidly execute investigator-initiated

kidney cancer clinical trials. Support from this award is directed toward Consortium infrastructure needs rather than direct support of the research itself.

Applicants are expected to demonstrate a broad understanding of kidney cancer research, including knowledge of the current state of clinical studies and clinical priorities related to kidney cancer and are encouraged to familiarize themselves with the KCRP's Strategic Plan, and to consider this material when preparing their application.

The anticipated direct costs budgeted for the entire period of performance for an FY19 KCRP Clinical Consortium Award will not exceed **$3M** for the Coordinating Center and will not exceed **$600,000** for each Clinical Trial Site. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

To facilitate global investigations, U.S. and international institutions are encouraged to apply. *Submissions from institutions with enhanced access to patients in the Military Health System and/or from disproportionately affected populations (including, but not limited to, socioeconomic status, access to health care, age, geography, race, and ethnicity) are especially encouraged*.

The FY19 KCRP Clinical Consortium Award mechanism is designed to fund a single Coordinating Center and a minimum of three Clinical Trial Sites (the Coordinating Center will count as one of the three Clinical Trial Sites), each through separate awards. Principal Investigators (PIs) will be required to indicate in the pre-application whether the institution is applying as either the Coordinating Center with a Clinical Trial Site or as a Clinical Trial Site only. The Coordinating Center and Clinical Trial Sites will be jointly responsible for proposing, selecting, and conducting Phase II and Phase I/II clinical trials focused on kidney cancer therapeutic interventions. The Coordinating Center and Clinical Trial Sites funded by the FY19 KCRP Clinical Consortium Award may work with additional Clinical Trial Sites that may be funded by the KCRP in future fiscal years. Additional details regarding the structure of the consortium are described below.

The Coordinating Center, in addition to functioning as a Clinical Trial Site, will serve as the Consortium information and planning nexus providing administrative, operational, and data management support services to participating Clinical Trial Sites to implement Consortium clinical trials in a timely manner. Responsibilities of the Coordinating Center will include coordinating the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. The Coordinating Center will also be responsible for preparing two clinical trials, with funding already secured, to be initiated by the Consortium within the first 6 months of the performance period. In addition, the Coordinating Center will coordinate and promote best practices for human subject recruitment and will aid Clinical Trial Sites in directing potential subjects to the most appropriate trials. All Sites (Clinical Trial Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials.

Collectively, the Coordinating Center PI, the PI from each Clinical Trial Site, and consumer advocates will constitute the Clinical Consortium Steering Committee. The consumer advocates

must be kidney cancer patients, or caretakers for someone with kidney cancer, and possess a high-level familiarity with current issues in kidney cancer research. The consumer advocates' role in the committee should be independent of their employment with a participating institution. During the Consortium's period of performance, the Coordinating Center PI will chair the Steering Committee. The Clinical Consortium Steering Committee will collaboratively develop and maintain a procedure for the selection of clinical trials to be implemented within the Consortium. The KCRP Grants Officer Representative (GOR) must be invited to meetings of the Clinical Consortium Steering Committee as well as any other formal meetings of the Consortium.

All Sites will be responsible for working collaboratively to identify new clinical trials for implementation. Any site may serve as an entry point for clinical trials that originate from outside the consortium. The Coordinating Center will be responsible for facilitating this entire process. The consortium should leverage other Department of Defense (DoD) investment opportunities whenever possible (e.g., to support correlative studies, clinical trial PIs are strongly encouraged to apply for translational awards offered by the DoD).

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 KCRP priorities.

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

Key requirements of the Clinical Consortium Award include:

1. **Responsibilities of the Consortium Participants:** Procedures for the Consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively. At the discretion of the Government, a pre-award planning meeting may be required.

    a. **Coordinating Center.** Responsibilities specific to the Coordinating Center include:

    ○ Adherence to the responsibilities delineated below for a Clinical Trial Site.

    ○ Coordination and facilitation of at least two open clinical trials at all times after the first 6 months of the performance period.

    ○ Development and maintenance of the Consortium organizational structure.

    ○ Provision of at least two initial interventional clinical trial protocols that will be open for recruitment by the Consortium within the first 6 months of the performance period.

- Management of Consortium-developed procedures for review, selection, and implementation of clinical trials proposed by or through Consortium members.

- Establishment and management of procedures to ensure compliance with the local institutional review boards (IRBs) of all Sites for the conduct of clinical trials and the protection of human subjects.

- Establishment and management of procedures for ensuring compliance with U.S. Food and Drug Administration (FDA) requirements for investigational agents, devices, and procedures.

- Establishment and management of a communications plan and an ongoing communications system between the Coordinating Center and Clinical Trial Sites.

- Management of Consortium-developed quality assurance and quality control mechanisms for study monitoring, including:

  - Real-time and remote monitoring program

  - Management plan for the handling, distribution, analysis, and banking of specimens and/or imaging products generated from Consortium studies necessary for the conduct and analyses of clinical trials during the performance period of the award

  - Registration, tracking, and reporting of participant accrual

  - Timely medical review and assessment of participant data

  - Rapid reporting and communication of adverse events

  - Interim evaluation and consideration of measures of outcome

- Management of Consortium-developed comprehensive data collection and data management systems that address the needs of all sites in terms of access to data, data security, and data integrity measures.

- Development of statistical plans for all Consortium clinical trials.

- Management of Consortium-developed intellectual and material property issues among institutions participating in the Consortium.

- Management of Consortium-developed procedures for the timely publication of major findings and other public dissemination of data.

- Development and execution of plans for ongoing review by the Consortium's External Advisory Board (EAB), to include participation by Government representatives. EAB reviews should be conducted no less than twice yearly.

b. Clinical Trial Sites. The responsibilities of each site include:

○ If required by the Government, participation in a pre-award planning meeting with all Consortium members to discuss operational features of the Consortium, the requirements for progress and evaluation, and the award negotiations process.

○ Full participation in the Consortium, including but not limited to, clinical trial introduction and selection, patient accrual for Consortium studies (to consider disproportionately affected populations [see https://seer.cancer.gov]), data collection and timely submissions, meeting attendance, and adherence to the Consortium's operating procedures.

○ Presentation of at least two clinical trials for the Consortium's consideration per year.

○ Meeting minimum accrual requirements of 25 patients per year for each open and recruiting clinical trial, either independently or in partnership with other non-Consortium institutions. At least 20% of these patients must be contributions to trials from other Consortium Sites, and at least 5% of all accrued patients at each site must be from disproportionately affected populations.

○ Provision for a Clinical Trial Coordinator, who will interact with the Clinical Trial Coordinators of other Clinical Trial Sites and the Supervising Clinical Trial Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes, to coordinate patient accrual and study activities across Sites, and foster communication with other Consortium Clinical Trial Coordinators.

○ Implementation of the Consortium's core data collection methodology and strategies.

○ Compliance with Consortium-developed quality assurance and quality control procedures, as appropriate, including:

– Participation in a monitoring program to be managed by the Coordinating Center.

– Implementation of the Consortium-developed management plan for acquisition, delivery, and storage of biological samples and study data.

– Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use.

○ Implementation of procedures established by the Coordinating Center for ensuring compliance with FDA requirements for investigational agents, as appropriate.

○ Implementation of procedures established by the Coordinating Center to meet the local IRB requirements for the conduct of clinical trials and the protection of human subjects.

- Participation in Consortium-developed procedures for the timely publication of major findings.

- Participation in Consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the Consortium.

- Participation in ongoing review by the Consortium's EAB.

- Submission of annual written progress reports, a final written comprehensive report, and any other reports required by the Government to be outlined in the assistance agreement.

- Additional responsibilities based on recommendations and guidance from the consortium EAB and U.S. Army Medical Research and Materiel Command (USAMRMC) staff.

2. **Performance Metrics**

Exercise of the options for continued performance of each participant site after the first year will be contingent upon meeting performance metrics as specified in the award agreements.

a. **Metrics for Coordinating Center Performance**

- Presentation of at least two clinical trials for the Consortium's consideration per year.

- Maintain a portfolio of at least two open trials per year after the first 6 months of the period of performance.

- Meeting minimum accrual requirements of 25 patients per year from each open and recruiting clinical trial, either independently or in partnership with other non-Consortium institutions. At least 20% of these patients must be contributions to trials from other Consortium sites, and at least 5% of all accrued patients at each site must be from disproportionately affected populations.

b. **Metrics for Clinical Trial Site Performance**

- Accrual of at least 25 patients per year to each open and recruiting clinical trial, either independently or in partnership with other non-Consortium institutions.

- Participation in a minimum of two trials per year initiated by any of the Consortium sites.

- Presentation of at least two trials per year to the Consortium for consideration.

- Timely submission of quality data as outlined by the Coordinating Center.

3. **Oversight of the Clinical Consortium Award**

An EAB composed of kidney cancer researchers and consumer advocates who are not involved with the Consortium and KCRP Programmatic Panel members will provide administrative and scientific guidance to the GOR; the EAB will be assembled by the Clinical Consortium Steering Committee. The EAB Chair and a representative from USAMRMC will be invited to regular meetings of the Clinical Consortium Steering Committee and must be provided agendas and minutes for these meetings. The Coordinating Center PI and Clinical Trial Site PIs must present written and oral briefings to the EAB at semi-annual 1-day meetings. Based on these reports and presentations, the GOR, with input from the EAB and USAMRMC staff, will evaluate progress, provide feedback, and recommend to the USAMRAA Grants Officer actions to be taken as needed to facilitate the success of the Clinical Consortium Award. The Coordinating Center PI may also be required to submit quarterly progress reports. The Coordinating Center and all Clinical Trial Sites will be required to submit a final comprehensive written report of the Consortium's accomplishments to the USAMRMC.

The CDMRP expects to allot approximately $7.68M over a 3-year period to fund approximately one Clinical Consortium – Coordinating Center and three Clinical Consortium – Clinical Trial Site Award applications. A total of $2.56M will be allocated from the FY19 KCRP budget to fund the first year of performance. Options will be included for continued performance in subsequent years, with $2.56M expected from each of the FY20 and FY21 KCRP budgets. The initial performance period of the award and each option period will be for 12 months. 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 initially funded with FY19 funds, which will expire for use on September 30, 2025. Exercise of the options for continued performance is contingent upon receipt of sufficient Congressional appropriations for the KCRP in FY20 and FY21, with anticipated funds expiring for use on September 30, 2026 and September 30, 2027, respectively.

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.

The assistance agreement for this funding opportunity will be a cooperative agreement, in which substantial DoD programmatic involvement with the recipient is anticipated during the performance of the project. Under the cooperative agreement, DoD's purpose is to support and stimulate the recipient's activities in and otherwise working jointly with the award recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the project. The dominant role and prime responsibility reside with the direct recipient for the project as a whole.

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 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.

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 Department of Veterans Affairs (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 PIs/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.

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

PIs must be independent investigators at or above the level of Assistant Professor (or equivalent) at an eligible institution. Eligibility is not affected by previous receipt of a KCRP Consortium Development Award.

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.

Each investigator may be named on only one Clinical Consortium Award application as PI.

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

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

II.D. Application and Submission Information

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

Extramural Submission: 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 PI 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.

When starting the pre-application, PIs should ensure that they have selected the appropriate application category:

- Clinical Trial Site, *or*

- Coordinating Center with a Clinical Trial Site, *or*

- Coordinating Center with a Clinical Trial Site with the option to be considered as a Clinical Trial Site only if the application is not selected for award as the Coordinating Center.

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 KCRP 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 (COIs)**

  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. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

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

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

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.

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-KCRP-CCA 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-KCRP-CCA 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.
Descriptions of each required file can be found under Full Application Submission Components: • 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)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **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	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your

Extramural Submissions	Intramural DoD Submissions
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. **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.	Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email.
[Application Verification Period](#)	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	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 *with the exception of the Project Narrative and Research & Related Budget Form*. 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.
Further Information	
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. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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 (60-page limit for the Coordinating Center; 20-page limit for each Clinical Trial Site): 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.

        - **Coordinating Center (40-page limit):** It is the PI's responsibility to clearly articulate the ability of his or her group to serve as the Consortium Coordinating Center and support the design and conduct of Consortium clinical trials.

Describe the qualifications of the group and plans for the development of key features of the Consortium Coordinating Center using the following general outline:

a. **Commitment to and Experience in Multidisciplinary and Multi-Institutional Kidney Cancer Clinical Research:** Describe previous experience and accomplishments of the PI and key personnel related to the design, administration, and fiscal management of multi-institutional kidney cancer clinical trials (with particular emphasis on Phase II), of high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer. Describe previous experience with establishing communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the application. If the institution is a previous recipient of a KCRP Consortium Development Award, a description of the past performance of that award must be included.

b. **Institutional Resources:** Include evidence of institutional commitment to provide the necessary resources needed to develop and support standardized data collection, data management and analysis, and data security and integrity for the Consortium participants.

c. **Consortium Organizational Structure:** Provide a detailed description of the overall Consortium organization, description of previous collaborations, plans for ongoing communications, procedures for transference of funds, and standardized operating procedures for selection and implementation of clinical trials. The organizational structure should include the following key features:

   – Coordinating Center for administration and day-to-day management of Consortium operations; developing the clinical trial selection process, protocol coordination; regulatory coordination; study management and monitoring; data collection, management, and statistics; intellectual/material property coordination; and performance as a Clinical Trial Site.

   – Clinical Trial Sites for conceiving, developing, and conducting clinical trials in kidney cancer, as well as serving as entry points for clinical trials from outside the Consortium.

   – Clinical Consortium Steering Committee composed of the PIs from the Coordinating Center and Clinical Trial Sites, for the clinical trial selection process and for the continual development and operation of the Consortium. A representative from the USAMRMC is to be invited to all official meetings for the Clinical Consortium Steering Committee.

   – Plans for ongoing communications among Clinical Trial Sites and between Clinical Trial Sites and the Coordinating Center; plans should address methods for information distribution within the Consortium, and how information technologies will be used to (1) facilitate routine multi-

institutional communication and (2) provide ongoing communication and data sharing.

- Evidence of past experience as a collaborating facility participating in a clinical trial focused in kidney cancer.

d. **Clinical Trial Implementation:** Describe plans for coordinating the submission, review, selection, and implementation of clinical trials within the Consortium.

- Outline plans for coordinating IRB submissions and approvals at participating Sites.

- Outline plans for developing procedures to ensure compliance with FDA requirements for investigational agents, as appropriate.

e. **Study Management and Monitoring:** Describe plans for ongoing communication among all institutions participating in the consortium.

- Include a **named** Supervising Clinical Trial Coordinator who will interact with, and oversee, the Clinical Trial Site clinical coordinators to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across Sites.

- Outline procedures for quality assurance, quality control, and study monitoring.

- Describe plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from Consortium-sponsored studies.

f. **Data Management:** Outline a strategy for the development and implementation of a comprehensive data management and statistical analysis plan, including:

- Descriptions of the overall approach to data collection and management.

- A statistical plan that includes methods to monitor quality control, quality assurance, and consistency of data collection and methods to measure outcomes.

- A plan for ongoing data transfer and ongoing communication.

- Data access, security, and integrity measures.

g. **Publication and Data Dissemination:** Describe plans for ensuring rapid publication and other public dissemination of data while maintaining participant privacy.

h. Fiscal Administration: Describe previous experience with the financial management of multi-institutional clinical research studies, including distribution and management of funds. Outline a detailed strategy for achieving financial self-sufficiency of the consortium by the end of the performance period for the Clinical Consortium Award.

i. Initial Clinical Trial(s): Start section on a new page; 10-page limit for this section within the 40-page limit for the Coordinating Center portion. Provide brief descriptions of a minimum of two currently funded Phase I or Phase II kidney cancer clinical trials for high-impact, novel therapeutic interventions proposed to be implemented by the Consortium within the first 6 months of the award period. This means the initial clinical trial(s) must be ready to initiate patient accrual just prior to or at the initiation of the award. The proposed studies will be evaluated at both peer and programmatic review.

Include the following information for each of the initially proposed clinical trials:

–   Clinical trial title: Provide the title of each clinical trial.

–   Phase: Designate the clinical trial as Phase I or II.

–   Personnel: List the names of all personnel (including the PI) who will have significant involvement in the clinical trials; include their practice license(s) (e.g., M.D. or R.N.), highest degree(s), job title(s), and employing institution(s).

–   Location of study: List all centers, clinics, or laboratories where the studies are to be conducted; include details as to how Consortium Clinical Trial Sites will be integrated into the trial(s).

–   Background: Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings; include descriptions of preliminary studies, Phase I results, or other findings.

–   Objectives: Describe the purpose, goals, and endpoint of the study.

–   Drug or device: Describe the drugs or devices to be used in the studies; include Investigational New Drug (IND)/Investigational Device Exemption (IDE) numbers, sponsors, and sources, if applicable.

–   Study population: Describe the target population and the proposed sample size and provide patient accrual rate requirements.

–   Protocol design: Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology.

- Timeline: Describe how the proposed study timeline indicates increased efficiency as a result of Consortium participation.

- Funding and IRB approval status: Provide evidence of funding status of the initial clinical trial(s); describe the status of IRB approval for the initial clinical trial(s).

- **All Sites (Coordinating Center and Clinical Trial Sites) (20-page limit):** It is the responsibility of the applicant to clearly articulate the qualifications of the research team and institution to participate as a Clinical Trial Site in the Consortium.

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the Consortium:

a. **Commitment to, and experience in, kidney cancer clinical research**

If the institution is a previous recipient of a KCRP Consortium Development Award, a description of the performance of that award must be included, with emphasis on the individual contribution of the institution to Consortium activities.

- Describe the PI's commitment to kidney cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.

- Describe the previous success of the PI and key personnel in acquiring funding for clinical trials.

- Describe the PI's experience in conducting multi-institutional clinical trials that demonstrate willingness and ability to function in the Consortium.

- Describe how the PI will integrate into the Consortium and be a contributing member.

- Describe how well the PI's institution has facilitated the PI's past and present collaborations.

- Describe specific areas of clinical research interest, such as novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies. Include overall scope of program and demonstration of integration of basic and/or correlative science into the program.

- Provide details of ongoing or completed kidney cancer-relevant clinical trials, particularly Phase II clinical trials, with an emphasis on clinical trials that might be brought into the Consortium. Reference relevant publications and submit reprints with the application.

- Describe procedures for ensuring compliance with FDA requirements for investigational agents.

- Provide evidence of willingness to resolve intellectual and material property issues.

- Provide details of the Supervising Clinical Trial Coordinator's appropriate expertise in the coordination of regulatory approvals and consortium activities.

b. Consortium resources

- Include a **named** institutional Clinical Trial Coordinator, who will interact with the Clinical Trial Coordinators at other Consortium Clinical Trial Sites and the Supervising Clinical Trial Coordinator at the Coordinating Center, to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, coordinate study activities across Sites, and foster communication with other Consortium Clinical Trial Coordinators.

- Describe the available kidney cancer population (including size, age range, and clinical manifestations) and provide evidence of ability to accrue kidney cancer patients into consortium-sponsored studies. Include documentation of, access to, and ability to recruit patients from disproportionately affected populations and any other special patient populations, such as those in the Military Health System.

- Provide evidence of successful multi-center clinical trial collaborations.

- Describe the development of the proposed EAB.

c. Institutional resources

- Provide evidence of expertise in clinical trials within the applicant institution and describe experience in the development and conduct of kidney cancer clinical trials; as appropriate, describe any additional multidisciplinary clinical and/or laboratory expertise that could serve as the basis for the development of clinical trials by the Consortium.

- Provide evidence of institutional success in recruiting patients for clinical trials.

- Describe the resources and expertise available for the collection and processing of specimens from Consortium-sponsored studies.

- Describe the resources and expertise for data management and maintenance of data security/confidentiality.

- Provide evidence of institutional commitment to providing facilities and resources in the conduct of Consortium operations.

Attachment 2: Supporting Documentation (Coordinating Center and Clinical Trials Sites): 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 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.

- 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.

  Note: As this award supports Consortium infrastructure and does not provide direct support for the clinical research, certain types of intellectual property may not be relevant to this application and need not be discussed.

  - 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.

- Clinical Trial Funding and Approval Documentation (Coordinating Center – applications only): Provide documentation of funding and IRB approval status for the initial clinical trial(s).

○ **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.

Describe the proposed Consortium or, for Clinical Trial Site applications, specific participation in the Consortium including the following elements:

- Background: Present the ideas and reasoning behind the proposed effort.

- Objective/Hypothesis: State the objectives to be achieved. Provide evidence that supports the feasibility.

- Specific Aims: State the specific aims.

- Study Design: Briefly describe the types of clinical trials to be proposed for conduct by the Consortium.

- Clinical Impact: Briefly describe how the proposed Consortium, or participation in the Consortium, may lead to a major impact on kidney cancer clinical management.

○ **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.

The lay abstract is required for Coordinating Center applicants only. Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

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

– Describe the ultimate applicability of the research.

– What types of patients will it help, and how will it help them?

– What are the potential clinical applications, benefits, and risks?

– What is the projected time it may take to achieve an impact on the standard of care for kidney cancer?

– What are the likely contributions of this study to advancing the field of kidney cancer research?

○ **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 Clinical Consortium 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 (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.

– Briefly state the methods to be used.

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

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

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other Government agency.

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe how the PI and other personnel will contribute to the productive operations of the Consortium and have an impact moving high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer to clinical practice.

Explain in detail why the proposed project is important, as follows:

Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed project, including a description of the target populations. Explain how these results/outcome(s)/product(s) will have the potential to transform kidney cancer management and change clinical practice.

Describe the long-term impact: Explain the long-term gains from the proposed project, including how the outcomes or products will ultimately contribute to the elimination of death from kidney cancer and enhancing the well-being of men experiencing the impact of the disease.

○ **Attachment 7: Data and Research Resource Sharing Plan (one-page limit): Upload as "Sharing.pdf".** Describe how unique and/or final research data will be shared with the wider kidney cancer research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the award. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan.

Refer to the General Application Instructions, Appendix 2, Section K, for additional information.

In preparing requested budgets, applicants may include anticipated costs associated with data- and research resource-sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).

○ **Attachment 8: 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 9: 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, 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".

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

  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 9. (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.

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 purpose of the KCRP Clinical Consortium Award is to provide the funding to establish the necessary collaborations and resources to rapidly execute clinical trials by the Consortium.

This award will not fund research or development of clinical protocols.

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

Coordinating Center

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$3M**. These funds are for all Coordinating Center functions, both administrative and clinical, as described in this Program Announcement. 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 **$3M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Clinical Trial Sites

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$600,000** for each Clinical Trial Site. 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 **$600,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Exercise of the options for continued performance for the Coordinating Center and for each Clinical Trial Site after the first year will be contingent upon meeting the performance metrics as outlined in the Section II.B, Award Information, and upon receipt of sufficient Congressional appropriations to the KCRP for FY20 and FY21.

For this award mechanism, **for the Coordinating Center**, direct costs must be requested for:

- Travel for attendance at EAB review meetings (including costs for all appropriate personnel), to be held up to two times per year. Costs should also include expenses incurred for conducting these meetings.

- Travel for the PI and up to four additional members of the research team to attend a 1-day meeting to be held in the National Capital Area **once** during the performance period of the award. This meeting is intended as a forum for the CCA team to present an update on progress.

The travel costs required above are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the consortium, such as the PI, Supervising Clinical Trial Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager

- Consortium-related meetings, teleconferences, and travel among participating investigators

- Database generation, software development, and website design

- Purchase of computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions

- Other costs directly associated with planning and developing the Consortium collaborations and resources

- Travel costs for up to two investigators to travel to two scientific/technical meetings per year, in addition to the required meeting described above, to present project information or disseminate project results

For Clinical Trial Sites, direct costs must be requested for:

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

May be requested for (not all inclusive):

- Salary support for personnel needed to meet the goals of the Consortium, such as the PI, Clinical Trial Coordinator, Research Nurse, and Data/Informatics Coordinator

- Consortium-related meetings, teleconferences, and travel among participating institutions

- Computers and general software required to participate in the Consortium

- Other costs directly associated with planning and developing the Consortium

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 initially funded with FY19 funds, which will expire for use on September 30, 2025. Exercise of the options for continued performance is contingent upon receipt of sufficient Congressional appropriations for the KCRP in FY20 and FY21, with anticipated funds expiring for use on September 30, 2026, and September 30, 2027, respectively.

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**:

- **Coordinating Center** *(to be reviewed in addition to the All Sites criteria below)*: All Coordinating Center applications will be evaluated according to the following criteria. Of these, Personnel, Consortium Components, and Study and Data Management are equally the most important, with the remaining criteria listed in decreasing order of importance.

  ○ **Personnel**

    – How well the PI or other key personnel have demonstrated appropriate expertise in kidney cancer and in the design and administration of multi-institutional kidney cancer clinical trials.

    – Whether the PI and key personnel have previous success in acquiring funding for clinical trials.

    – Whether the Supervising Clinical Trial Coordinator, who will interact with all Clinical Trial Coordinators, possesses the appropriate expertise to coordinate regulatory approvals and consortium activities.

  ○ **Consortium Components**

    – Whether the application includes all required Consortium components (e.g., Clinical Consortium Steering Committee, Coordinating Center, and Clinical Trial Sites, including affiliates).

    – How well the components as proposed will function as an integrated unit.

    – How well the proposed EAB has been developed.

  ○ **Study and Data Management**

    – How the strategies for the development and implementation of data management and statistical plans will provide access to data, data security, and data integrity.

    – Whether there is an outline of an appropriate study management plan, including plans for ongoing communication, quality control, and quality assurance.

    – Whether there are appropriate plans for the development of specimen handling, distribution, analysis, and banking methods.

- Whether there are appropriate plans for rapid publication and other public dissemination of data generated by the Consortium.

- Whether all relevant privacy issues have been addressed appropriately.

○ **Financial Management**

- Whether the PI and/or other key personnel have appropriate experience and expertise in fiscal administration of multi-site studies, including the distribution and management of funds.

- How well the Coordinating Center personnel demonstrate ability and commitment to achieving financial self-sufficiency of the Consortium by the end of the award period.

○ **Coordinating Center Initial Clinical Trial(s)**

- **Personnel (applicable if a clinical trial(s) originates from outside the Coordinating Center and key personnel have not been previously listed)**

  ▪ Whether the PI and other key personnel in the clinical trial have been named and whether they have the appropriate expertise in kidney cancer.

  ▪ Whether the PI has a proven record of success in completing clinical trials.

- **Study Design**

  ▪ Whether the trials are focused on potentially high-impact, novel, therapeutic interventions.

  ▪ Whether the study population has been adequately described.

  ▪ Whether the investigational drugs or devices have been adequately described.

  ▪ If from outside the Coordinating Center, whether the initiating institution(s) possess the appropriate qualifications.

  ▪ Whether the proposed timelines indicate increased efficiency as a result of Consortium participation.

- **Regulatory Process**

  ▪ Whether the trials will be ready for initiation at a time appropriate for implementation by the consortium.

  ▪ Whether there are appropriate plans for the coordination of IRB submissions and approvals at participating Sites.

  ▪ Whether there is an appropriate plan for developing procedures to ensure compliance with FDA regulations for investigational agents.

- ▪ Whether the appropriate IND/IDE numbers have been provided.

  - – **Impact**

    - ▪ Whether the trials address an important problem in kidney cancer.

    - ▪ To what extent the intervention or device to be tested will have a significant impact on kidney cancer, if the study is successful.

    - ▪ Whether the types of studies proposed are appropriate.

- **All Sites (Clinical Trial Sites and Coordinating Center):** All applications will be evaluated according to the following criteria, which are of equal importance.

  - ○ **Personnel**

    - – Whether the PI meets the eligibility requirements.

    - – How the research team's background and expertise are appropriate with respect to its ability to perform multi-institutional kidney cancer clinical research.

    - – To what extent the research team has the ability and experience to contribute substantially to the design and conduct of Consortium clinical trials.

    - – Whether the named institutional Clinical Trial Coordinator has the appropriate experience in guiding clinical protocols through the regulatory approval processes, to coordinate patient accrual and study activities across Sites, and the ability to foster communication with other Consortium Clinical Trial Coordinators.

    - – Whether there are appropriate levels of effort for successful conduct of the proposed work. If applicable, whether the description of past performance of a previously received KCRP Consortium Development Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to Consortium activities.

  - ○ **Institutional Resources and Commitment**

    - – Whether the institution has demonstrated appropriate commitment to working with the Consortium.

    - – How the PI is supported by the availability of and accessibility to facilities and resources, especially with regard to specimen collection and processing.

    - – Whether the institution possesses appropriate resources and expertise for data management and maintaining security and confidentiality.

    - – How well the institution has demonstrated its willingness and ability to resolve intellectual and material property issues with other institutions in the Consortium.

- Whether the institution has unique resources that may be of benefit to the Consortium.

○ **Participant Recruitment**

- Whether the PI has demonstrated sufficient access to the appropriate kidney cancer patient population(s).

- Whether the PI has provided sufficient evidence of access to, and the ability to recruit patients from disproportionately affected populations.

- Whether the PI has provided evidence of access to, and the ability to recruit patients from other special populations, such as those from the Military Health System (if applicable).

- Whether the institution has proven success in recruiting patients for clinical trials.

○ **Collaborations**

- Whether the PI has demonstrated appropriate background, expertise, and success in collaborative kidney cancer clinical research.

- How well the PI will integrate into the Consortium and be a contributing member.

- How well the PI's institution has facilitated the PI's collaborations.

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.

- **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 KCRP, as evidenced by the following:

  ○ Adherence to the intent of the award mechanism

  ○ Program portfolio composition

  ○ 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 KCRP 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 and anticipated FY20-FY21 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.

Organizational transfers will not be allowed for the Coordinating Center or Clinical Trial Sites under the Clinical Consortium Award mechanism.

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

II.F.1.b. Pre-Award Meeting

At the Government's discretion, the PI and Clinical Study Coordinator or other personnel may be requested to participate in a pre-award meeting at the Government's expense.

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.

Additionally, quarterly progress reports may be required at the discretion of the Government.

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 20190218e. The Program Announcement numeric version code will match the General Application 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 application:

- An FY19 KCRP 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 KCRP Programmatic Panel members can be found at https://cdmrp.army.mil/kcrp/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 may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn 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.

- Failure of the PI(s) to meet the eligibility criteria.

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"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Data and Research Resource Sharing Plan: Upload as Attachment 7 with file name "Sharing.pdf"	
	Representations (Extramural submissions only): Upload as Attachment 8 with file name "RequiredReps.pdf" if applicable	
	DoD Military Budget Form(s): Upload as Attachment 9 with file name "MFBudget.pdf" if applicable	
Research & Related Personal Data	Complete form as instructed	
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	

Application Components	Action	Completed
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	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CCA	Clinical Consortium Award
CDA	Consortium Development Award
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
EAB	External Advisory Board
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
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
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/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