

# **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 – Clinical Trial Site Award**

**Announcement Type: Modified**

**Funding Opportunity Number: W81XWH-20-KCRP-CTSA**

**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 2, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, September 23, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, September 28, 2020
- **Peer Review:** November/December 2020
- **Programmatic Review:** January/February 2021

*This Program Announcement must be read in conjunction with the General Application Instructions, version 501. 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 2020 (FY20) 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 FY19 totaled \$45 million (M). The FY20 appropriation is \$40M.

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 mechanism was first offered in FY19. Since then, one Clinical Consortium Award - Coordinating Center application has been received and was recommended for funding. Additionally, five Clinical Consortium Award – Clinical Trial Site applications have been received. Of those applications, three have been recommended for funding.

### **II.B. Award Information**

This year the KCRP is offering the Clinical Consortium – Clinical Trial Site Award (CTSA) mechanism to support the inclusion of new Clinical Trial Sites to the existing Kidney Cancer Research Consortium (KCRC). The FY20 KCRP CTSA 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 CTSA 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 should be knowledgeable of the current state of clinical studies and clinical priorities related to kidney cancer and are encouraged to familiarize themselves with the [KCRP Strategic Plan](#), and to consider this material when preparing their application.

The FY20 KCRP CTSA mechanism is designed to fund up to two new Clinical Trial Sites, each through separate awards. FY19 KCRP CTSA awardees are not eligible to apply for this FY20 KCRP CTSA. The Clinical Trial Sites will merge with the newly established KCRC and will be jointly responsible for proposing, selecting, and conducting Phase II and Phase I/II clinical trials focused on kidney cancer therapeutic interventions. The existing Consortium consists of one Coordinating Center and three Clinical Trial Sites. Additional details regarding the structure of the Consortium are described below.

The Coordinating Center, in addition to functioning as a Clinical Trial Site, serves 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 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. In addition, the Coordinating Center coordinates and promotes best practices for human subject recruitment and aids Clinical Trial Sites in directing potential subjects to the most appropriate trials. All Sites (Clinical Trial Sites and the Coordinating Center) are required to participate in at least two of the KCRC's new or ongoing clinical trials at all times.

Collectively, the Coordinating Center Principal Investigator (PI), the PI from each Clinical Trial Site, and consumer advocates 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 KCRC's period of performance, the Coordinating Center PI chairs the Steering Committee. The Clinical Consortium Steering Committee collaboratively develops and maintains procedures 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 KCRC.

All Sites are 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 is responsible for facilitating the 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 FY20 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 FY20 KCRP Clinical Consortium – Clinical Trial Site Award are listed below. Additional information regarding the responsibilities of the current KCRC Coordinating Center can be found within the FY19 KCRP Program Announcement [W81XWH-19-KCRP-CCA](#) on pages five and six.

- **Responsibilities of the Consortium Participants:** Procedures for the Consortium, while managed 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.
  - **Coordinating Center.** The responsibilities of the established Coordinating Center for the KCRC can be found within the FY19 KCRP Program Announcement [W81XWH-19-KCRP-CCA](#) on pages five and six.
  - **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 15 patients per year across open and recruiting KCRC clinical trials, 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 Institutional Review Board (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 External Advisory Board (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 Development Command (USAMRDC) staff.

- **Performance Metrics:** Exercise of the option for continued performance of each participant Site after the first year will be contingent upon meeting performance metrics as specified in the award agreements.
  - **Metrics for Clinical Trial Site Performance**
    - Accrual of at least 15 patients per year across open and recruiting Consortium clinical trials, either independently or in partnership with other non-Consortium institutions.
    - Participation in a minimum of two trials, at all times, 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.

The types of awards made under the Program Announcement will be assistance agreements. An assistance 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. 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. 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, but is not limited to, 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 anticipated direct costs budgeted for the entire period of performance for an FY20 KCRP Clinical Consortium – Clinical Trial Site Award will not exceed **\$300,000 per year** for a maximum of **\$600,000** for the entire 2-year performance period. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$1.92M over a 2-year period to fund approximately two Clinical Consortium – Clinical Trial Site Award applications. A total of \$960,000 will be allocated from the FY20 KCRP budget to fund the first year of performance. Options will be included for continued performance in the following year, with \$960,000 expected from each of the FY21 KCRP anticipated Congressional appropriations. The initial performance period of the award and the following 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 FY20 funding opportunity will be initially funded with FY20 funds, which will expire for use on September 30, 2026. Exercise of the option for continued performance is contingent upon receipt of sufficient Congressional appropriations for the KCRP in FY21, with anticipated funds expiring for use on September 30, 2027.*

**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 USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.* 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. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

**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. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

## **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, 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. ***Intramural Submission: Application submitted by a DoD organization for an intramural investigator working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.***

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

### **II.C.1.b. Principal Investigator**

Principal Investigators must be independent investigators at or above the level of Assistant Professor (or equivalent) at an eligible institution.

Each investigator may be named on only one Clinical Consortium – Clinical Trial Site Award application as a PI.

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

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

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

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

## **II.D. Application and Submission Information**

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

### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

### ***Intramural DoD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org)

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

## **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.

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*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1. Full Application Guidelines](#)).

***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](mailto: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](mailto:help@eBRAP.org) or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI 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 applicant must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

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

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/Program.htm>. 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.

[FY20 KCRP Programmatic Panel members](#) should not be involved in any pre-application or refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest 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 kidney cancer clinical trial environment, patient population, and PI’s experience with conducting kidney cancer-focused clinical studies. 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.

*Do not password protect any files of the application package, including the Project Narrative.*

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
<p>Download application package components for W81XWH-20-KCRP-CTSA from Grants.gov (<a href="https://www.grants.gov">https://www.grants.gov</a>) 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.</p>	<p>Download application package components for W81XWH-20-KCRP-CTSA from eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</p>
<b>Full Application Package Components</b>	
<p><b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.</p>	<p><b>Tab 1 – Summary:</b> Provide a summary of the application information.</p> <p><b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<p><b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <p><b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>
<b>Application Package Submission</b>	
<p><b>Create a Grants.gov Workspace.</b> Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit”</p>	<p><b>Submit package components to eBRAP</b> (<a href="https://ebrap.org">https://ebrap.org</a>).</p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> 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</p>

Extramural Submissions	Intramural DoD Submissions
<p>button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> 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 <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p>press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><u><a href="#">Application Verification Period</a></u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

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. *It is important to include the attachment name as a header on each page of the attachment files.*

- **Attachment 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

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. Describe the proposed project in detail using the outline below.

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

– **Consortium resources**

- Include a *named* institutional Clinical Trial Coordinator, who will interact with the Clinical Trial Coordinators at other 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.

- **Institutional resources**
  - Provide evidence of experience in clinical trials within the applicant institution and describe this experience in the development and conduct of kidney cancer clinical trials; as appropriate, describe any additional multidisciplinary clinical and/or laboratory experience that could serve as the basis for the development of clinical trials by the KCRC.
  - 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: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- 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.
- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

Describe the 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 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.

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 effort 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 likely contributions of the effort 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 FY20 KCRP Clinical Consortium – Clinical Trial Site Award mechanism, use the SOW format example titled,

“SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
  - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
  - Briefly state the methods to be used.
  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- **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 effect 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 Resources 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: Suggested Collaborating DoD Military Budget Format, 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 a separate budget, using “Suggested Collaborating DoD Military Facility Budget Format”, 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”.
  - Include Clinical Trial Site Coordinator’s biographical sketch.
- 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 “Suggested Collaborating DoD Military Facility Budget Format” 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.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

#### **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**

***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. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** 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.

***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 will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

#### **II.D.5. Funding Restrictions**

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. A total of \$300,000 in direct cost will be allocated from the FY20 budget to fund the first year of performance for each Clinical Trial Site. Option will be included for continued performance in the subsequent year with \$300,000 direct costs expected from the FY21 budget to fund the option year. The initial performance period of the award and following option period will be for 12 months each. ***Exercise of the option for continued performance is contingent on receipt of sufficient Congressional appropriations to the KCRP in FY21 and acceptable performance by the recipients***, as outlined in [Section II.B, Award Information](#). 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.

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

For this award mechanism, direct costs must be requested for:

- **EAB Review meetings:** Travel costs for the PI and one additional member of the research team to present project information or disseminate project results at a 1-day EAB Review meeting during the period of performance in year **2**, **up to \$1,800 per person**, should be requested. For planning purposes, it should be assumed that the meeting will be held **in the National Capital Area**. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- 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:
  - PI

- Clinical Trial Coordinator
- Research Nurse
- Data/Informatics Coordinator
- Consortium-related meetings, teleconferences, and travel among participating institutions
- Computers and/or software required to participate in the KCRC
- Other costs directly associated with participating in the KCRC

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.*

#### **II.D.6. Other Submission Requirements**

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

### **II.E. Application Review Information**

#### **II.E.1. Criteria**

##### **II.E.1.a. Peer Review**

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

- **Personnel**
  - How the research team's background and experience 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, ability 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 key personnel to enable the successful conduct of the proposed work.

- **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.

- **Participant Recruitment**

- Whether the applicant has demonstrated sufficient access to the appropriate kidney cancer patient population(s).
- Whether the applicant has provided sufficient evidence of access to, and the ability to recruit patients from, disproportionately affected populations.
- Whether the applicant 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, experience, and success in collaborative kidney cancer clinical research.
- How well the PI will integrate into the KCRC 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 FY20 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, USAMRDC, 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>. An 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 FY20 funds are anticipated to be made no later than September 30, 2021. 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.

**Pre-Award Costs:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

***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.

#### **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 under the Clinical Consortium – Clinical Trial Site 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, Clinical Study Coordinator, and/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 [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.

The Award Terms and Conditions will specify if more frequent reporting is required.

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](mailto: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](mailto:support@grants.gov)

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the Program Announcement 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 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

### **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 FY20 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 FY20 KCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/kcrp/panels/panels20>.*

- 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 FY20, 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.
- FY19 KCRP CTSA awardees are not eligible to apply for this FY20 KCRP CTSA.
- The PI does not 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 ( <b>Extramural submissions only</b> )	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>Intramural submissions only</b> )	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 Resources 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	
	Suggested Collaborating DoD Military Facility Budget Format: 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 Suggested Collaborating DoD Military Budget Format, including 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
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
CTSA	Clinical Consortium – Clinical Trial Site Award
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
IRB	Institutional Review Board
KCRC	Kidney Cancer Research Consortium
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs