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: Modified

Funding Opportunity Number: HT9425-23-KCRP-CCA

Assistance Listing 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), October 26, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, November 14, 2023
- **Peer Review:** December - January 2023
- **Programmatic Review:** March 2024

This program announcement must be read in conjunction with the General Application Instructions, version 803. 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 2023 (FY23) Kidney Cancer Research Program (KCRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC).

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 FY22 totaled $185 million (M). The FY23 appropriation is $50M.

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

II.A.1. FY23 KCRP Overarching Strategic Goals

The KCRP's vision is to eliminate kidney cancer through collaboration and discovery. The mission of the FY23 KCRP is to promote rigorous, innovative, high-impact research in kidney cancer for the benefit of Service Members, Veterans, and the American public. Within this context, the KCRP is interested in supporting research and clinical care that addresses the KCRP Overarching Strategic Goals to: (1) increase understanding of the biology of kidney cancer; (2) develop novel therapeutic strategies for the treatment of kidney cancer; (3) improve patient care for kidney cancer patients; and (4) grow the field and increase collaboration in the area of kidney cancer.

Applicants are strongly encouraged to read and consider the KCRP Strategic Plan, which includes further information on the overarching goals and program priorities, before preparing their applications. The KCRP Strategic Plan may be found at https://cdmrp.health.mil/kcrp/default.

II.A.2. Focus Areas

Clinical Consortium Award applications ***must address at least one of the FY23 KCRP Focus Areas***, as presented below. **Selection of the Focus Area(s) is the responsibility of the applicant.**

- Conduct basic biology research to better understand etiology and cancer progression, metastatic disease, refractory disease and therapeutic resistance, genetic and environmental risk factors, and the prevention of kidney cancer.

- Identify and develop new strategies for screening, early-stage detection, and accurate diagnosis and prognosis prediction of kidney cancers, with examples including biomarkers and imaging, treatment of early-stage cancers.

- Define the biology of rare kidney cancers and develop treatments to improve outcomes and reduce death.
- Develop novel therapeutic strategies for the treatment of kidney cancer, such as novel drug targets, therapeutic modalities and agents, treatment combinations, and drug delivery systems.
- Identify and implement strategies to improve the quality of life and survivorship for patients.
- Identify and implement strategies to mitigate health disparities, such as access to healthcare, social and cultural factors, environmental factors, and biological contributors.
- Increase research capacity through support and development of research conducted by the next generation of kidney cancer researchers, or patient care in alignment with the FY23 KCRP Overarching Strategic Goals.

Disease Subtype: Applicants must select the kidney cancer type that the study seeks to address.

- Clear cell renal cell carcinoma (ccRCC)
- von Hippel-Lindau (VHL)-associated with kidney cancer
- Papillary RCC
- Chromophobe RCC
- Collecting duct carcinoma
- Translocation RCC
- Renal medullary carcinoma (RMC)
- Transitional cell carcinoma (TCC)
- Wilms tumor (nephroblastoma)
- Renal sarcoma
- Angiomyolipoma
- Oncocytoma
- Not classified/not applicable

Focus Area(s) and Disease Subtype are used for program analysis purposes.

II.A.3. Award History

The KCRP Clinical Consortium Award mechanism was first offered in FY19.

In FY20, the Clinical Consortium Trial Site Award was offered.

II.B. Award Information

The Clinical Consortium Award mechanism provides support to develop and enhance collaborations and resources necessary for a network of organizations to rapidly execute phase 2 or phase 2-linked phase 1 (phase 1/2) kidney cancer clinical trials. These trials will include investigations of high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer. Applicants are expected to demonstrate a broad understanding of kidney cancer research, including knowledge of the current state of clinical studies and priorities related to kidney cancer, and are encouraged to familiarize themselves with the FY23 KCRP's Overarching Strategic Goals and Focus Areas and to consider this material when preparing their application. Support from this award is to be directed toward Consortium infrastructure needs rather than direct support of the trials themselves.

The principal goal of the KCRP Clinical Consortium Award is to combine the efforts of leading investigators to bring to market high-impact, novel, therapeutic strategies and interventions to improve patient outcomes and significantly decrease the impact of the disease. To facilitate global investigations, U.S. and international institutions are encouraged to apply. ***Submissions from institutions with access to patients from high-risk, underserved, and/or military populations (as described in the FY23 KCRP Overarching Strategic Goals and Focus Areas) are especially encouraged***.

The FY23 Clinical Consortium Award mechanism will be used to select and fund six Clinical Research Sites and one Coordinating Center. PIs will be required to indicate whether the institution is applying as either the Coordinating Center with a Clinical Research Site or as a Clinical Research Site only. Institutions applying as the Coordinating Center, if not selected for funding, have the option to still be considered as a Clinical Research Site only. The Coordinating Center and Clinical Research Sites will be jointly responsible for proposing, selecting, and conducting phase 2 and phase 1/2 clinical trials focused on kidney cancer therapeutic interventions. The Coordinating Center and Clinical Research Sites funded by the FY23 KCRP Clinical Consortium Award will work with additional Clinical Research 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 Research Site, will serve as the Consortium information and planning nexus providing administrative, operational, and data management support services to participating Clinical Research 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 and management, statistical support, and intellectual/material property coordination. The Coordinating Center will also be responsible for launching 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 Research Sites in directing potential subjects to the most appropriate trials. ***All Sites (Clinical***

Research Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials.

Collectively, the Coordinating Center Principal Investigator (PI), the PI from each Clinical Research Site, and consumer advocates will constitute the Clinical Consortium Steering Committee. The Steering Committee can also have other members, such as representatives from the other partner organizations and industry. The consumer advocates must be kidney cancer patients or caregiver 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 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 clinical research and correlative studies, PIs are strongly encouraged to apply for clinical trial and/or translational awards offered by the DOD).

Key requirements of the Clinical Consortium Award include:

- **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. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included. At the discretion and expense of the government, a pre-award planning meeting may be required.
    - **Coordinating Center:** Responsibilities specific to the Coordinating Center include:
        - Adherence to the responsibilities delineated below for a Clinical Research Site
        - Coordination and facilitation of at least eight clinical trials at any given time after the first 12 months of the performance period
        - Development and maintenance of the Consortium organizational structure
        - Provision of at least two initial clinical trial protocols for implementation 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 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 Research 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 a plan for financial sustainability leveraging collaborations, industry sponsors, and/or other funding opportunities to allow Consortium activities to continue beyond the award period of performance

- Presentation of written and/or oral briefings to the KCRP Programmatic Panel and USAMRDC staff at 1-day meetings typically held in the Baltimore-Washington, DC area.

- **Clinical Research 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 include accrual from high-risk, underserved, and/or military populations), 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. ***For the Coordinating Center, this requirement is in addition to the initial two clinical trials required at the beginning of the award.***

  - In accordance with Consortium-developed guidelines, maintain a minimum combined accrual across all Consortium-associated studies as well as a maximum contributed percentage for each individual study.

  - Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Research Sites and the Supervising Clinical Research Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across sites.

  - 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; and

    - 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.

- Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies).
- 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.
- 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 USAMRDC staff.

- **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. All references to clinical trials in the outlined responsibilities are specific to phase 2 or phase 1/2 trials; phase 3 or higher clinical trials are not included.

  The Consortium Steering Committee will determine appropriate overall minimum and maximum accrual metrics for the Clinical Trial Sites per trial as part of the Consortium Standard Operating Procedures. Each Clinical Trial Site is expected to have the ability to enroll adequate numbers of evaluable individuals with kidney cancer per year into the Consortium studies OR to provide such unique expertise or facilities to otherwise justify inclusion as a site.

  - **Metrics for Coordinating Center Performance:**
    - Implementation of at least four trials in the initial 12-month period of the award period of performance.
    - Maintain a portfolio of at least eight open trials at any given time after the first 12 months of the period of performance.
    - Successfully move agents for at least 20% of Consortium trials forward for additional testing (e.g., phase 3), which ultimately have the potential to change clinical practice. **Note:** The Clinical Consortium Award is not intended to support the conduct of clinical trials that test the next logical iteration of an existing treatment.
    - Enrollment of at least 5% of patients from high-risk, underserved, and/or military populations (as described in the FY23 KCRP Overarching Strategic Goals and Focus Areas) in Consortium trials overall.

        - High risk populations include, but are not limited to, groups that may have the genetic predisposition or lifestyle that place individuals at higher risk of renal cancer.

        - Underserved populations include, but are not limited to, racial/ethnic groups that have higher incidence of renal cancer, lower socioeconomic status, and/or difficulty of access to care.

    - **Metrics for Clinical Research Site Performance:**

        - Enrollment of the adequate number of individuals with kidney cancer per trial each year as determined by the Consortium Steering Committee. Each Clinical Research Site is expected to participate in a minimum of eight trials initiated within Consortium over 4 years.

        - Presentation of at least two trials per year or eight trials over 4 years to the Consortium for consideration.

        - Accrual of at least 5% of patients from high-risk, underserved, and/or military populations (as described in the FY23 KCRP Overarching Strategic Goals and Focus Areas).

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

- **Plan for Financial Sustainability:** It is expected that the collaborations and infrastructure developed under the Clinical Consortium Award will continue past the period of performance on this award. Coordinating Center applications must include a plan for financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow Consortium activities to continue beyond the award period of performance.

- **Past Performance (if applicable):** Applications from institutions that have previously received a KCRP Clinical Consortium Award must include a description of the past performance of the award, including compliance with the metrics of the previous award as well as other individual contributions made to Consortium activities. If past performance was directly affected by the COVID-19 pandemic, and/or other significant event (e.g., natural disaster), describe its impact on performance metrics and how those issues would be resolved or mitigated to increase performance for the new award.

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, the 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 FY23 KCRP priorities.

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 proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research which is of significance to the warfighter, military families, and the American public.

The CDMRP expects to allot approximately $10.8M (direct costs) to fund approximately one Coordinating Center and approximately six Clinical Research Site Clinical Consortium Award applications. The anticipated direct costs budgeted for the entire period of performance for an FY23 KCRP Clinical Consortium Award should not exceed **$6M for the Coordinating Center of $0.8M for each Clinical Research Site**. ***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 FY23 funding opportunity will be initially funded with FY23 funds, which will expire for use on September 30, 2029.***

The KCRP plans to invest approximately $17.28M (direct plus indirect costs) in the Clinical Consortium Award over a 4-year period. The KCRP will allocate $3.2M (direct plus indirect costs) to the Coordinating Center and $0.64M (direct plus indirect costs) to each Clinical Research Site from the FY23 appropriation. Options for the Coordinating Center for continued performance will be included in subsequent years pending funding from the FY24, FY25, and FY26 appropriations. Options for the Clinical Research Sites for continued performance will be included pending funding from the FY25 appropriation. ***Exercise of the options for continued performance is contingent on receipt of congressional appropriations to the KCRP in FY24–FY26 and acceptable performance by the recipients.*** Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), 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 application submission is ***not*** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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.

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

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical research are in vitro studies that utilize human tissues that cannot be linked to a living individual.
Note: Studies that meet the requirements for exemption under §46.104(d)(4) of the Common Rule are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA 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 foreign organizations, foreign public entities, and 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 organizations 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:*** **An *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.***

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

II.C.1.b. Principal Investigator

Independent investigators with a faculty-level appointment (or equivalent) are eligible. Eligibility is not affected by previous receipt of a KCRP Clinical Consortium Award.

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

The CDMRP strongly 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).

Inclusion of classified research data within the application and/or proposing research of which the anticipated outcomes may be classified or deemed sensitive to national security concerns may result in application withdrawal. Refer to the General Application Instructions, Appendix 2, Section E.

II.D.1. eBRAP and Grants.gov

The electronic Biomedical Research Application Portal (eBRAP) (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (https://grants.gov), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

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

Extramural Submission:

- 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 Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at 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.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, 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 eBRAP 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 eBRAP Help Desk at 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 and mentor(s) identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

- **Tab 1 – Application Information**

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

  FY23 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 eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a 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 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. An invitation to submit is ***not*** required.

- **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

Applications will not be accepted unless a LOI has been received.

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://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
Application Package Location	
Download application package components for HT9425-23-KCRP-CCA from Grants.gov (https://grants.gov) and create a Grants.gov Workspace. Workspace allows online completion	Download application package components for HT9425-23-KCRP-CCA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
of the application components and routing of the application package through the applicant organization for review prior to submission.	
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	**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 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 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	**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 Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DOD Submissions
ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	
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.

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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (60-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 (uniform resource locators) 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.

    1. **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 2), 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 Research Site.

- Clinical Research 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 and consumers from the Coordinating Center and Clinical Research Sites, for the clinical trial selection process and for the continual development and operation of the Consortium. A representative from the USAMRDC is to be invited to all official meetings for the Clinical Consortium Steering Committee.

- Plans for ongoing communications among Clinical Research Sites and between Clinical Research 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 on 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 Research 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 acquiring funding for clinical trials, and with the financial management of multi-institutional clinical research studies. Outline a detailed strategy for achieving financial sustainability that leverages collaborations, industry sponsors, and/or other funding opportunities to allow consortium activities to continue beyond the award period of performance.

i. **Two 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 1 or phase 2 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 1 or 2.

- 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 Research 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 1 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; describe how they meet the mechanism intent of supporting investigation of high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer. Include Investigational New Drug (IND)/Investigational Device Exemption (IDE) application numbers, sponsors, and sources, if applicable. Describe the procedures that will ensure compliance with FDA regulations for investigational agents.

- Study population: Describe the target population and the proposed sample size and provide patient accrual rate requirements. Describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects, if applicable.

- Protocol design: Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology. Include a description of the proposed timelines for the study, emphasizing points that demonstrate increased efficiency of the study as a result of Consortium participation.

- 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), including plans for the coordination of IRB submissions and approvals at participating sites.

- Impact: Describe anticipated outcomes of the proposed study and the potential impact of the intervention or device, if successful, in addressing the FY23 KCRP Overarching Strategic Goals and Focus Areas and effect on kidney cancer patient care.

2. **All Sites (Coordinating Center and each Clinical Research Site) (20-page limit per site):** It is the responsibility of the applicant to clearly articulate the qualifications of the research team and institution to participate as a Clinical Research 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 an FY19 KCRP Clinical Consortium Research Site Award, whether as Coordinating Center or Clinical Research Site, a description of the performance of that award must be included, including performance related to the previous award metrics, and a description of the individual contribution(s) of the institution to Consortium activities. If past performance was directly affected by the COVID-19 pandemic, and/or other significant event (e.g., a natural disaster), describe its impact on performance metrics and how those issues will be resolved or mitigated to increase performance for the new award.

      - 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 experience of the PI and other key members of the research team in conducting collaborative, multi-institutional clinical trials that demonstrate willingness and ability to function in the Consortium.

      - Describe the experience of the PI and other key members of the research team in conducting collaborative, multi-institutional clinical trials that demonstrate willingness and ability to function in the Consortium.

      - Describe the research team's ability and experience to contribute substantially to the design and conduct of Consortium clinical trials. Describe specific areas of clinical research interest, such as novel drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies; explain the relevance and potential impact on the FY23 Overarching Strategic Goals and Focus Areas. 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 Research 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 Research 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 participation in successful multi-center clinical trial collaborations.

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: 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 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 (two-page limit per letter):** 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) (two-page limit per letter):** Provide a signed letter from each collaborating individual, consumer(s)/ caregiver(s) or organization demonstrating 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 the 2 CFR 200.315, "Intangible Property."

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

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

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

- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instruction 3200.12.

  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.

- **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.

- Inclusion of Women and Minorities (Coordinating Center only): For each of the initial clinical trials described in the application, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and

ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **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 Research 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 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***. ***Do not duplicate the technical abstract.*** 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 the Coordinating Center and each individual research site. 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 the proposed trials to advancing the field of kidney cancer research and patient care?

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** The suggested Statement of Work (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). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the Clinical Consortium Award, refer to either the "***Suggested SOW Strategy for Clinical Research_Clinical Trial***" or "***Suggested SOW Strategy Generic Research***", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW 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".** Explain in detail the anticipated impact of the applicant's participation in the Consortium as follows:

  - Describe the short-term impact: Explain how the research team's areas of clinical research interest will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer. Detail the anticipated outcomes from the institution's participation in Consortium-led clinical trials, including the potential impact the institution is expected to have in recruiting patients from high-risk, underserved, and/or military populations to Consortium-led studies. Explain how these results/outcome(s)/ product(s) will have the potential to impact the FY23 KCRP Overarching Strategic Goals.

  - Describe the long-term impact: Explain the long-term gains from the research team's contributions to the Consortium, including how the outcomes or products will ultimately contribute to the elimination of death from kidney cancer and enhancing the well-being of Service Members, Veterans, and all the men and women and their families who are 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.

- **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 Facility 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 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 1681[a] 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".

    - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

    - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

  - 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".

    - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

    - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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.

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).

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. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. ***As of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.*** 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

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 KCRP plans to invest in the Clinical Consortium Award over a 4-year period, using the FY23 appropriation to fund the first year of Coordinating Center performance and the first two years of Clinical Research Site performance. Options for the Coordinating Center will be included for continued performance in subsequent years, pending FY24, FY25, and FY26

appropriations. An option for the Clinical Research Sites will be included for an additional 2-year period of continued performance, pending FY25 appropriations.

The initial performance period of the award and each option period will be 12 months for the Coordinating Center. The initial performance period of the award and the option period will be 24 months for the Clinical Research Sites.

Exercise of the options for continued performance is contingent on receipt of congressional appropriations to the KCRP in FY24–FY26 and acceptable performance by the recipients.

The maximum period of performance is 4 years.

Coordinating Center

- The maximum period of performance is 4 years, with an initial 12-month period followed by up to three 12-month option periods.
- The direct costs budgeted for the entire period of performance should not exceed $6M. 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.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

Clinical Research Sites

- The maximum period of performance is 4 years, with an initial 24-month period followed by one 24-month option period.
- The direct costs budgeted for the entire period of performance for a Clinical Research Site should not exceed $0.8M. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate.
- All direct and indirect costs of any subaward or contract (subgrant or subcontract) must be included in the total direct costs of the primary award.

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

- Travel costs for the PI and up to four additional research team members to present project information or disseminate project results at a KCRP program meeting **each year** during the period of performance. 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.

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 Research Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager
- Implementation of Consortium-developed standardization plan, data management program, real-time communications system, and administration plans for the Consortium
- Consortium-related meetings, teleconferences, and travel among participating investigators
- Purchase of computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions
- Purchase of minor equipment and consumables necessary for specimen collection and transfer, and data storage and transfer
- Costs associated with using Consortium Core facilities
- Costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms
- Research-related subject costs to include costs associated with specimen collection and biobanking from Clinical Trials executed through the Consortium
- Correlative research costs associated with Clinical Trials executed through the Consortium
- Costs related to establishing financial sustainability (e.g., fees for legal consultation)
- Other costs directly associated with planning and developing the Consortium

  Costs for up to two investigators to travel to one or two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the KCRP Consortium Award Mechanism.

Must not be requested for:

- Cost of intervention/drug

Direct costs for each **Clinical Research Site** may be requested for (not all-inclusive):

- Salary support for personnel needed to meet the goals of the Consortium such as the PI, Clinical Research 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

- Costs for up to two investigators to travel to one or two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the KCRP Consortium Award Mechanism

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:

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 there are appropriate levels of effort for successful conduct of the proposed work.

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

- **If applicable,** whether the description of past performance of a previously received KCRP Clinical Consortium Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to Consortium activities; whether past performance was directly affected by the COVID-19 pandemic and/or other significant event, how well the site describes plans to resolve of mitigate those issues to increase performance for the new award.

- **Consortium Components**

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

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

  - To what degree the appropriate resources are provided for full participation at each Consortium Site.

  - How effectively the Consortium has established methods of making payments to Consortium members, the means of ensuring and overseeing member's efforts on research projects, provisions for member's resource sharing contributions, and provisions for ownership and rights in intellectual property developed previously or under the agreement.

- **Data Management**

  - Whether the degree to which the overall approach to data collection, management, analysis, and security measures is appropriate.

  - Whether the PI and key personnel have demonstrated effective application of methods to monitor quality and consistency of data collection, and methods to measure outcomes in previously conducted clinical trials.

  - Whether the plan is adequate for real-time data transfer with regard to supporting the Consortium-associated activities.

  - 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.
    - How adequate the plan is for real-time data transfer with regard to supporting the Consortium-associated activities.
    - How appropriate the plans are for real-time communication among all organizations participating in the Consortium, including complete and timely reporting, review, and appropriate responses to adverse events (including suspension of a trial, modification of a trial protocol, or cessation of a trial) in facilitating Consortium activities.
    - Whether the named Clinical Research Coordinator has the appropriate experience with guiding clinical protocols through the regulatory approval processes, coordinating participant accrual, and coordinating study activities across sites.
    - How adequate the outlined procedures are for quality assurance, quality control, safety, and study monitoring with regard to conducting multi-institutional clinical studies.
    - How appropriate the plans are for specimen handling, distribution, analysis, banking, and security with regard to facilitating Consortium activities.

- **Financial Management**
    - Whether the PI and/or other key personnel have appropriate experience and expertise in fiscal management of multi-institutional clinical research studies.
    - 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.
    - The extent to which the applicant has demonstrated access to the resources proposed as part of their resource share.

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 conducting and completing kidney cancer clinical trials.

- How appropriate are the ability and experience of the coordinating center with financial management of multi-institutional research studies?

- **Study Design**
  - Whether the trials are focused on potentially high-impact, novel, therapeutic interventions.
  - Whether the study population has been adequately described.
  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research in each trial.
  - Whether the investigational drugs or devices have been adequately described.
  - If the Clinical Research Site originates 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 application numbers have been provided.

- **Impact**
  - Whether the trials address one of the FY23 Overarching Strategic Goals and/or Focus Areas.
  - To what extent the intervention or device to be tested, if the study is successful, will have a significant impact on kidney cancer.

All Sites (Clinical Research 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 Research Coordinator has the appropriate experience in guiding clinical protocols through the regulatory approval processes and the ability to foster communication with other Consortium Clinical Research 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 Clinical Consortium Award demonstrates successful achievement of previous award metrics and other substantive individual contributions to Consortium activities; if past performance was directly affected by the COVID-19 pandemic and/or other significant event, how well the site describes plans to resolve or mitigate those issues to increase performance for the new award.

- **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 ability to recruit patients from high-risk, underserved, and/or military populations.

  - 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.
- **Impact**
    - To what extent the research team's areas of clinical research interest, if successfully developed, will support the presentation of clinical trials to evaluate high-impact, novel therapeutic agents or approaches for the management or treatment of kidney cancer.
    - To what degree the anticipated outcomes from the institution's participation in the Consortium, including the expected recruitment of patients from high-risk, underserved, and/or military populations to Consortium-led studies, will impact Consortium-led clinical trials and the FY23 KCRP Overarching Strategic Goals and/or Focus Areas.

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

- **Budget**
    - Whether the **direct** maximum costs exceed the allowable direct maximum costs as published in this 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 Defense Health Program and FY23 KCRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition

- Programmatic relevance to FY23 KCRP Overarching Strategic Goals
- 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. ***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.health.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 200.1, 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 FY23 funds are anticipated to be made no later than September 30, 2024. 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 the 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, other non-profit, or for-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.A.5.

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.

The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

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

At the government's discretion, the Coordinating Center PI, Clinical Research Site lead PIs, and Clinical Research Manager 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 and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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 whether additional and/or more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

(Coordinating Center Only) Public Health Service (PHS) Inclusion Enrollment Reporting Requirement ***(only required for clinical research studies and clinical trials)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail 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 $10M 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. These 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. eBRAP 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 eBRAP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET (closed on most U.S. federal holidays). 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 eBRAP 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 803a. The program announcement numeric version code will match the General Application Instructions version code 803.

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 FY23 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 FY23 KCRP Programmatic Panel members can be found at https://cdmrp.health.mil/kcrp/panels/panels23.***
- 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 FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.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.
- Application includes research data that are classified and/or proposes research of which the anticipated outcomes may be classified or deemed sensitive to national security will be considered for application withdrawal.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- The application does not address one of the FY23 KCRP Focus Areas.

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 (Coordinating Center submissions only): 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"	
	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	
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field	

Application Components	Action	Completed
Budget **(intramural submissions only)**	Suggested 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	
Additional Application Components	**Action**	**Completed**
Confidential Letters of Recommendation	Confirm upload to eBRAP	

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CCA	Clinical Consortium Award
ccRCC	Clear Cell Renal Cell Carcinoma
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	Food and Drug Administration
FY	Fiscal Year
IACUC	Institutional Animal Care and Use
IDE	Investigative Device Exemption
IND	Investigative New Drug
IPR	In-Progress Review
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RCC	Renal Cell Carcinoma
RMC	Renal medullary carcinoma
SAM	System for Award Management

SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TCC	Transitional cell carcinoma (TCC)
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
VHL	von Hippel-Lindau