

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

Academy of Kidney Cancer Investigators – Leadership Award

Announcement Type: Initial

Funding Opportunity Number: HT942524KCRPAKCILA

**Assistance Listing Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), August 29, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, September 19, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, September 24, 2024
- **Peer Review:** November 2024
- **Programmatic Review: Stage 1:** January 2025
- **Invitation for Oral Presentation:** January 2025
- **Programmatic Review: Stage 2:** March 2025

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Kidney Cancer Research Program (KCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the KCRP in 2017 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the KCRP from FY17 through FY23 totaled \$235 million (M). The FY24 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. FY24 KCRP Overarching Strategic Goals

The KCRP's vision is to conquer kidney cancer through collaboration and discovery. The mission of the FY24 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:

- Increase understanding of the biology of kidney cancer.
 - Encourage innovative ideas with high impact.
- Develop novel therapeutic strategies for the treatment of kidney cancer.
 - Identify new targets.
 - Develop pharmacological, immunological, genetic, microbiome, or other interventions.
 - Optimize prognostic or predictive markers to assist with therapeutic decision-making.
 - Repurpose existing and currently approved drugs.
- Improve patient care for kidney cancer.
 - Integrate bench research with bedside care and emphasize translational research.
 - Invest in early-career kidney cancer physicians – next generation.
 - Facilitate multi-site collaborative clinical research development and clinical trials.

- Eliminate disparities in populations with an unequal burden of kidney cancer.
- Grow the field and increase collaboration in the area of kidney cancer.
 - Invest in next-generation kidney cancer physicians and scientists.
 - Facilitate multi-site collaborative clinical research development and clinical trials.
 - Encourage experts inside and outside the field of kidney cancer to apply knowledge for advancements.
 - Foster collaborations that cross translational, disciplinary, and institutional boundaries.

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. FY24 KCRP Focus Areas

To meet the intent of the funding opportunity, applications must address at least one of the FY24 KCRP focus areas, as presented below. Selection of the focus area(s) is the responsibility of the applicant. 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 treatments for all types of kidney cancer.
- 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 health care, social and cultural factors, environmental factors, and biological contributors.
- Increase capacity and multidisciplinary research through support and development of the next generation of kidney cancer researchers to improve patient care.

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

II.A.3. Award History

The Academy of Kidney Cancer Investigators- Leadership Award was only offered in FY19. One application was received, and one was recommended for funding.

II.B. Award Information

The Academy of Kidney Cancer Investigators (AKCI) is a unique, interactive virtual academy that provides, intensive mentoring, national networking, and a peer group for scientist and clinician junior faculty. The KCRP created the Academy of Kidney Cancer Investigators in FY19 to align with several program priorities, which *include to build research capacity in kidney cancer; increase collaborations to advance kidney cancer research, and support innovative research conducted by the next generation of kidney cancer scientists and clinicians*. The overarching goal of the AKCI is to increase research capacity in kidney cancer through the development of successful, highly productive kidney cancer researchers in a collaborative research and training environment.

The AKCI is a virtual career development and research training platform that currently consists of 11 Early-Career Scholars (ECS)/Designated Mentor pairs from different institutions, and one Academy Director. It is expected that six Early-Career Scholars will graduate by the fall of 2025 and four FY23 AKCI – Early-Career Scholars/Designated Mentor awards will be made by September 2024. In addition, Academy graduates will continue to participate in the annual Academy meetings. Information about the Academy is available on the KCRP webpage and in the Kidney Cancer Program Booklet at <https://cdmrp.health.mil/kcrp>. The AKCI leadership

team will identify opportunities for engagement with KCRP AKCI Scholars-Designated Mentors and KCRP FY25 (and subsequent year awardees) Postdoctoral and Clinical Fellowship Awardees. The Academy Director and Deputy Director catalyze the growth and professional development of the Early-Career Scholars in collaboration with their Designated Mentors, assess the progress of the ECSs, and facilitate communication and collaboration among all of the Academy members. The AKCI leadership team will also identify and offer opportunities for engagement (e.g., invitations to seminar series and in-person meetings) with FY24 Postdoctoral and Clinical Fellowship Awardees with FY24 KCRP AKCI-ECS-Designated Mentors (and subsequent year awardees).

This FY24 funding opportunity is soliciting applications for an Academy Director (Principal Investigator [PI]) and Deputy Director (Partnering PI) to lead the AKCI. The newly selected FY24 Academy Director and Deputy Director will initiate their responsibilities no later than October 2025. The Academy Director and Deputy Director (hereafter referred to as Academy Leadership) must be established kidney cancer researchers and can be at different institutions. The Academy Leadership must demonstrate a strong record of mentoring and training early-career investigators, a commitment to leadership, the ability to articulate methods toward research collaborations, and the ability to objectively assess the progress of all Scholars with their Designated Mentors in the AKCI. Other objectives will include execution of research that will engage AKCI FY24 Scholars (including subsequent-year Scholars), develop tools for Scholars to enable success, and provide opportunities to broaden their knowledge in kidney and renal pelvis cancers. The leadership team will identify and offer occasion(s) for the AKCI to network with KCRP FY24 Postdoctoral and Clinical Fellowship Awardees (and subsequent year awardees).

Designated Mentors on FY24 KCRP AKCI – Early-Career Scholar Award applications and Designated Mentors on open FY19 through FY23 KCRP AKCI – Early-Career Scholar Awards (with the exception of those graduating in 2024) are not eligible to apply for this award.

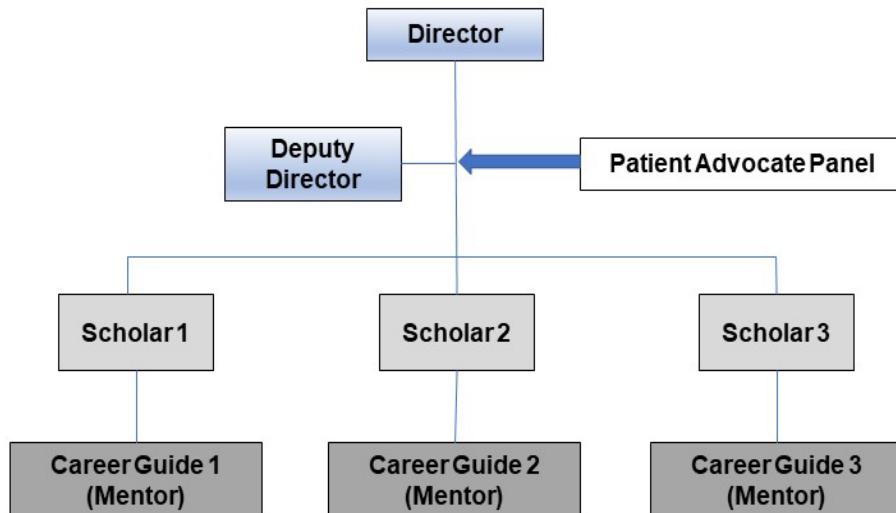


Figure 1: Example structure of the FY24 KCRP Kidney Cancer Research Consortium: Academy Director and Deputy Director will be the AKCI – LA Leadership

Note: An invited oral presentation is a requirement for application review of the KCRP AKCI – LA, as described in Section II.D.2.b.iv, Additional Application Components.

Responsibilities of the Academy Leadership include, but are not limited to:

- Act as a resource for all Scholars and Designated Mentors in the Academy over the Scholars' 4-year period of performance.
- Facilitate communication and collaboration among all Scholars and Designated Mentors (including periodic interactive communication among all Academy members).
- Develop assessment criteria to evaluate the research progress made by all Scholars, as well as their career progression and sustainment as independent investigators in kidney cancer research.
- Conduct collaborative kidney cancer pilot project(s) that include Academy Scholars. These pilot projects should have the potential to improve collaboration within the Academy, as well as impact kidney cancer research and/or kidney cancer patients/survivors.
 - Examples of pilot research projects may include but are not limited to (a) funding an extended statistical or bioinformatics analysis with AKCI Scholars, (b) performing a large-scale meta-analysis of human or animal datasets with AKCI scholars, (c) provide access to critical biorepositories or animal models to expand AKCI investigator analyses or increase study rigor.
- Provide constructive critiques with the goal of advancing the research and professional careers of the Scholars and strengthening the mentorship of the Designated Mentors.
- Provide avenues to increase the promotion of the Academy and visibility of Scholars within kidney cancer research and advocacy communities (e.g., peer review, conferences, editorial boards).
- Support the professional development, to include laboratory management skills, of the Scholars into leading researchers through invited presentations by experts outside of the AKCI – LA.
- Plan and host an annual 1-day workshop and, biennially, a multi-day workshop for all Scholars/Designated Mentor pairs as well as Academy graduates to present their research, share knowledge, and develop collaborative efforts within the AKCI. **Scholars will be responsible for their own travel costs to in-person Academy meetings.**
- Include KCRP FY24 Postdoctoral and Clinical Fellowship Awardees in at least one meeting of the FY24 AKCI. These investigators will be responsible for their own travel costs, funds for which are included in their research awards.
- Establish a panel of patient advocates and Veteran(s) (i.e., the Patient Advocacy Panel) to inform the AKCI on the needs of the patient community.

- Establish the Designated Mentor Panel to facilitate collaborations among the AKCI participants including the Scholars, Academy Director/Deputy Director, and the Designated Mentors.

The Academy of Kidney Cancer Investigators – Leadership Award is structured to support two PIs. The Academy Director will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The Deputy Director will be identified as the Partnering PI. The collaboration between the Academy Director and the Deputy Director should be supported by complementary expertise and experience. Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); however, both PIs should contribute significantly to the development of the proposed research project. The application should clearly demonstrate that both PIs have equal levels of input on the proposed Academy Leadership and clearly define the components to be addressed by each to support the success of the Scholars. While it is up to the Academy Director and the Deputy Director to define their roles, both Academy Leaders should have interactions with each Scholar-Designated Mentor pair, (and the Scholars’ Designated Mentors); acting as administrative support does not fulfill the intent of the Director and Deputy Director.

If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PI(s), refer to [Section II.D.2, Content and Form of the Application Submission](#).

Organizational-Level Emphasis:

The following areas of emphasis are broadly applicable to many CDMRP programs, not just the KCRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research, addresses the FY24 KCRP strategic priorities and/focus areas described in [Section II.A.1](#) and [Section II.A.2](#).

Nuclear Medicine: Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

Women’s Health: CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women’s health outcomes and/or advancing knowledge for women’s health.

Metastatic Cancer Task Force: A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional->

[Testimonies/2018/05/03/Metastatic-Cancer-Research](#)) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 KCRP priorities.

Rigorous Study Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (<https://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies.

Military Service Involvement: Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique 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.

Clinical trials are not allowed under this funding opportunity.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

- (1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#).

The funding instrument for awards made under the program announcement will be cooperative agreements (31 USC 6305). Substantial CDMRP programmatic involvement with recipients is anticipated during the performance of award activities. Substantial involvement means that, after award, CDMRP staff will assist, guide, coordinate, or participate in project activities including but not limited to:

- Participating in the Steering Committee that oversees study conduct.
- Make recommendations for continued funding based on (a) overall study progress, including sufficient patient and/or data accrual; (b) cooperation in carrying out the research (e.g., attendance at Steering Committee meetings, implementation of group decisions, compliance with the terms of award and reporting requirements); and/or (c) maintenance of a high quality of research.

The anticipated combined direct costs budgeted for the entire period of performance for a FY24 KCRP AKCI – LA should not exceed **\$1,500,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately \$2.4M to fund approximately one KCRP Academy of Kidney Cancer Investigator Leadership Award application (consisting of an Initiating PI application and a Partnering PI application). Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 and FY26 funds, which will expire for use on September 30, 2030, and September 30, 2032, respectively.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible *organizations*, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

Academy Director and Deputy Director:

- Must be an independent, established kidney cancer researcher at or above the level of associate professor or equivalent.
- Must have kidney cancer research funding (past and/or present).
- Must have a record of kidney cancer publications in peer-reviewed journals.
- May be a research- or physician-scientist.

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a *pre-application* submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a *full application* (eBRAP.org or

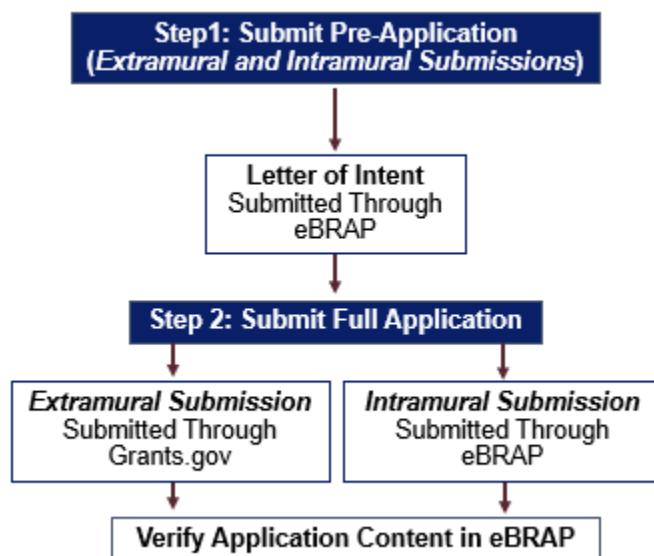
Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (<https://ebrap.org>) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (<https://grants.gov>) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524KCRPAKCILA from Grants.gov (<https://grants.gov>). Full applications from extramural organizations **must** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for

HT942524KCRPAKCILA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at <https://cdmrp.health.mil/funding/researchDup>.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 KCRP Programmatic Panel members should not be involved in any pre-application or full 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.

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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

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

Partnering PI: After the Initiating PI (Academy Director) confirms submission of the pre-application, the Partnering PI (Deputy Director) will be notified of the pre-application submission via an email from eBRAP. The Partnering PI must follow the link in the notification

email to associate the partnering preapplication with their eBRAP account. If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

Partnering PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the focus area under which the application will be submitted. Briefly describe integration of a Patient Advocacy Panel including the names of individuals participating.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. *An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.*

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations **must** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit

through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

Partnering PI: The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. The associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.

Each application submission must include the completed full application package for this program announcement. See [Section II.H.3](#) of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form (*Extramural Submissions Only*): Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands 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.

- **Vision:** Describe the Academy Leadership’s (Academy Director and Deputy Director) vision of the AKCI and how it will serve as a non-traditional, non-conventional training and research platform, including intensive mentoring and networking for the Scholars in a virtual environment. Describe the mission and roadmap as to how the Academy will develop highly productive kidney cancer researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 5-year period of performance. Articulate the overall goals of the AKCI with respect to the FY24 KCRP focus area(s).

- **Background and Experience:** Describe the Academy Leadership’s background and experience as established kidney cancer researchers. Describe the record of mentoring and training of early-career investigators and how this mentorship contributed significantly to the early investigators’ careers. Explain how the complementary experience of both candidates contributes to the ideal leadership of the Academy.
- **Management of the Academy:** Clearly define the roles that will be filled by the Academy Director and Deputy Director in leading the AKCI. Describe how the Academy Leadership will facilitate communication and collaboration among all of the Scholars and their Designated Mentors (including periodic but not limited to virtual interactive meetings and annual and biennial in-person workshops), as well as the kidney cancer research and advocacy communities. Explain how the Academy Leadership will develop and communicate the criteria that will be used to evaluate the research progress made by all of the Scholars, as well as their career progression and sustainment as independent investigators in kidney cancer research. Identify measurable outcomes for the Scholars that are expected to be achieved by the end of their 4-year period of performance and how they will contribute to the professional development of the Academy members. Explain how the Academy Leadership will help the Scholars overcome the barriers in initiating and sustaining a career in kidney cancer research (e.g., grant writing, research and laboratory management, publications, professional networking, and committee memberships). Describe the integration of the FY25 Postdoctoral and Clinical Fellowship awardees into the program to support potential collaborations with the Scholars.
- **Commitment to the Academy of Kidney Cancer Investigators:** Describe the Academy Leadership’s commitment to leading the AKCI and to the success of this unique, interactive virtual academy in providing collaborative mentoring of Scholars with the goal of developing sustainable, independent careers as leaders in kidney cancer research at their institutions, nationally, and internationally.
- **Scholar Transition Support:** Describe how the Academy Leadership will foster the transition of a Scholar from post terminal degree to assistant professor (or equivalent) and on up to independent scientist with a track record of independent funding.
- **Research Projects:** Describe a minimum of three pilot projects proposed by the Academy Leadership that will be conducted in a collaborative effort by the Academy Leadership and Scholars. Describe the scientific rationale of the pilot projects. List the specific aims and rationale as to why these pilot projects will help launch a career in kidney cancer. Address potential problem areas and present alternative methods and approaches. If applicable, describe how the proposed research using animals meets the regulatory guidelines for appropriateness and robustness of experimental design.
 - If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Clearly

describe the tissue or tumor type to be studied, where applicable (e.g., encapsulated versus diffuse plexiform neurofibroma).

- If the proposed research involves access to active-duty military and/or VA patient populations and/or DOD or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to the General Application Instructions, Appendix 4, for additional considerations.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. 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.
- **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:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (*if applicable*):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural

DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing 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.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP's expectations for making data and research resources publicly available.

KCRP Research Resources Initiative: The KCRP will make available to the scientific community a research resource list. The KCRP Research Resource will be located on the KCRP homepage <https://cdmrp.health.mil/kcrp>. Investigators are urged to leverage and contribute to these resources and include a sharing and distribution plan in the application within the Data and Research Resources Sharing Plan (Attachment 2).

- **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 signed by 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. If the VA-affiliated non-profit corporation is not identified as the applicant organization 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 Enrollment Plan (*only required if clinical research is proposed*):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.
- o **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.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

- **Academy Leadership Plan**

As Academy Leadership, describe your vision for the successful continuation of the Academy as a non-traditional, non-conventional training platform in which the Scholars will develop partnerships, collaboration, and career growth to ensure their dedication and productivity as leading kidney cancer researchers.

- **Research Plan:** Present the ideas and reasoning behind the proposed work.
- **Background:** Present the scientific rationale behind the proposed research project.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Provide supporting evidence or rationale.
- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Describe the study design, including appropriate controls.
- **Impact:** Describe how the proposed research will make an important contribution toward the goal of conquering kidney cancer.
- o **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

Lay abstracts should address the points outlined below *in a manner that will be readily understood by readers without a background in science or medicine.* Avoid overuse of scientific jargon, acronyms, and abbreviations.

- Describe the rationale for the proposed project in a manner that will be *readily understood by readers without a background in science or medicine.*
- Describe the Academy Leadership Plan.
 - As Academy Leadership, describe your vision for the successful continuation of the Academy as a non-traditional, non-conventional training platform in which the Scholars will develop partnerships, collaboration, and career growth to ensure their dedication and productivity as leading kidney cancer researchers.
- Describe the integration of patient advocates on the Patient Advocacy Panel.
- How will the data and resources generated during the performance of the proposed research project be shared with the research community (scientific and advocacy organizations) and the public?
- Describe the potential impact of the Academy toward advancing kidney cancer research and improving patient care, and/or quality of life for those living with kidney cancer.
- o **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Academy of Kidney Cancer Investigators – Leadership Award, refer to “Example: Assembling a Generic Statement of Work” for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.

- **Attachment 6: Sample Agenda (two-page limit): Upload as “SampleAgenda.pdf”.** Provide a sample agenda for the first annual workshop of a fully integrated Academy of Leadership and Scholars, which will be led by the FY24 Academy Leadership. Explain how the format for the workshop is designed to stimulate the professional growth of the Scholars in both leadership and research skills.
- **Attachment 7: Patient Advocacy Panel (three-page limit): Upload as “PatAd.pdf.”** Include the names of at least two patient advocates and at least one Veteran (the Veteran may be one of the patient advocates). Describe the Patient Advocacy Board. Articulate the patient advocates’ and/or Veteran(s)’ roles on the panel and how they will be integral to the training, networking, and collaboration of the Scholars. Clearly articulate how the patient advocates and Veteran(s) will have a meaningful role in the KCRP. Provide a letter from at least two patient advocates confirming their commitment to serving on the Patient Advocacy Panel.
- **Attachment 8: Impact Statement (one-page limit): Upload as “Impact.pdf”.** State explicitly how the proposed research project addresses one or more of the [FY24 KCRP Focus Area\(s\)](#) or, if the project does not address a focus area, provide justification that the proposed research project addresses a critical problem in kidney cancer research and/or patient care. In lay language, describe how the KCRP will bridge the gaps in patient outcomes and care through the multidisciplinary training and support of the next generation of kidney cancer researchers. Justify the long-term impact of the virtual academy on kidney cancer research. Describe how the [FY24 KCRP Focus Area\(s\)](#) are integrated into the Academy. Describe how the data and resources generated during the performance of the proposed research project will be shared with the research community (scientific and advocacy organizations) and the public.
- **Attachment 9: Animal Research Plan: Upload as “AnimalResPlan.pdf”.**
(Attachment 9 is only applicable and required for applications proposing animal studies.)

If the proposed study involves animals, a summary describing the animal research that will be conducted must be included in the application. Consult the ARRIVE guidelines 2.0 (Animal Research: Reporting *In Vivo* Experiments) to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines 2.0 can be found at <https://arriveguidelines.org/arrive-guidelines>. The Animal Research Plan may not be an exact replica of the protocol(s) submitted to the Institutional Animal Care and Use Committee (IACUC). The Animal Research Plan should address the following points to achieve reproducible and rigorous results for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
 - Summarize the procedures to be conducted. Describe how the study will be controlled.
 - Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
 - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
 - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Attachment 10: Representations (*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 8, Section B, Representations.
- **Attachment 11: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) **Research & Related Subaward Budget Attachment(s) Form (*if applicable, Extramural Submissions Only*):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

II.D.2.b.iii. Full Application Submission Components for the Partnering PI (Academy Deputy Director)

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

(a) **SF424 Research & Related Application for Federal Assistance Form (*Extramural Submissions Only*):** Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 10: Representations (Extramural submissions only):** Upload as “RequiredReps.pdf”.
 - **Attachment 11: Suggested Intragovernmental/Intramural Budget Form:** Upload as “IGBudget.pdf”.
- (c) **Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.
- (d) **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.
 - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.
- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.
- The Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.
- (g) **Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 12.

Additional Application Components

In addition to the complete application package, Kidney Cancer Academy of Kidney Cancer Investigators – Leadership Award applications also require the following components:

Oral Presentation

Candidates for Academy Director and Deputy Director selected for Stage 2 Programmatic Review will be required to give an oral presentation (see [Section II.E.1.b, Programmatic Review](#)). In the event a PI is invited to the Programmatic Review, Stage 2 (see [Section II.E.1.b, Programmatic Review](#)), but is unable to attend, CDMRP Staff and the Grants Officer will consider alternative arrangements on a case-by-case basis.

Each presentation will include a 30-minute talk by the candidates (Academy Director/Deputy Director pairs), followed by a 20-minute question-and-answer session with KCRP Programmatic Panel members. The following questions will be the topics for discussion during the PIs’ talk and the question-and-answer session. PIs who are selected should prepare a presentation consisting of no more than 10 slides (not including title slide) that specifically address the following:

- What conceptual or intellectual barriers do you consider as important to overcome in the career development and sustainment of investigators dedicated to kidney cancer research?
- Articulate the capabilities of the Academy Leadership to facilitate the Scholars’ development of partnerships, collaborations, and career growth to ensure their dedication, commitment, and productivity as leading researchers in kidney cancer.
- What are the proposed milestones and outcomes for the Scholars during the 4 years in the Academy?
- Briefly introduce your proposed kidney cancer pilot research project(s) that will be conducted as collaborative efforts with the Scholars. Briefly describe the metrics used to evaluate the outcomes of the research.
- Explain the significance of the Patient Advocacy Panel and illustrate how it will be integrated into the program.
- Briefly introduce the Academy Leadership team’s communication strategies to promote the Academy, to maximize networking opportunities/new research collaborations among scholar-mentor pairs and/or kidney cancer experts; and patients/patient advocacy groups.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.* Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

II.D.5. Funding Restrictions

The maximum period of performance is **5 years**.

The application’s combined direct costs budgeted for the entire period of performance should not exceed **\$1,500,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **5 years**.

A separate award will be made to each PI's organization.

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

- **Interim (In-Progress) Review (IPR)/Milestone Meetings:** Travel costs for the PI(s) for attendance and participation in at least one 2-day IPR should be requested.
- Costs associated with pilot research project(s) that will engage AKCI FY24 Scholars (including subsequent-year Scholars), develop tools for Scholars to enable success, and provide opportunities to broaden their knowledge in kidney and renal pelvis cancers.
- Costs associated with planning and holding the annual 1-day workshop (virtual or in-person) with Academy members, including costs associated with external speakers. (Do not include travel costs for the FY25 KCRP Postdoctoral and Clinical Fellowship Award; their travel costs will be covered by their FY25 KCRP Postdoctoral and Clinical Fellowship Award.)
- Costs associated with planning and holding the biennial multi-day in-person workshop in coordination with the KCRP staff, including costs associated with external speakers. In alternate years, they must also attend a DOD KCRP AKCI 1-day workshop. (Do not include travel costs for the FY25 KCRP Postdoctoral and Clinical Fellowship Award; their travel costs will be covered by their FY25 KCRP Postdoctoral and Clinical Fellowship Award.)
- These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Costs associated with establishing and maintaining a “virtual” academy (e.g., hardware and/or software for audio- or video-teleconferencing or web-based communications)
- Support for multidisciplinary collaborations, including travel.
- Travel between/among institutions participating in the Academy.
- Travel costs per Academy Leader to 1-day and biennial multi-day workshops.
- Travel costs per Academy Leader to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project outcomes or disseminate project results.

Must not be requested for:

- Clinical trial costs
- Tuition

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are listed in decreasing order of importance:

- **Academy Leadership**
 - To what extent the Academy Director's and Deputy Director's background and experience in kidney cancer research demonstrate their potential for leadership of the AKCI.
 - To what extent the Academy Leadership's record of mentoring and training early-career investigators in kidney cancer research indicates the potential for successful mentorship and career development of the Scholars.
 - To what degree the mentorship of the Director or Deputy Director contributed to the careers of past mentees.
 - How appropriate the levels of effort are for successful conduct of the proposed work.
- **Vision**
 - To what extent the vision of the AKCI supports the ideal to serve as a non-traditional, non-conventional training and research platform, including intensive mentoring and networking for the Scholars in a virtual environment.
 - Whether the mission and roadmap as to how the Academy will develop highly productive kidney cancer researchers who will be recognized as leading researchers through a collaborative and interactive research training environment within the 4-year period of performance is articulated and feasible.
 - Whether the overall goals of the KCRP with respect to the [FY24 KCRP Focus Area\(s\)](#) are described.
- **Management of the Academy**
 - Whether the roles that will be filled by the Academy Director and Deputy Director are clearly defined.

- How well the Academy Leadership demonstrates commitment to leading the AKCI and to the success of the unique, interactive virtual academy.
 - To what degree the Academy Leadership will facilitate communication and collaboration among all the Scholars and their Designated Mentors (including periodic but not limited to virtual interactive meetings and annual and biennial in-person workshops), as well as the kidney cancer research and advocacy communities.
 - How well the Academy Leadership developed the criteria that will be used to evaluate the research progress made by all Scholars and how the evaluation will be communicated to the Scholars.
 - To what degree the Academy Leadership will evaluate career progression and sustainment of Scholars as independent investigators in kidney cancer research.
 - Whether measurable outcomes are identified for Scholars and whether they are achievable within the 4-year period of performance.
 - To what extent the Academy Leadership will help the Scholars overcome the barriers in initiating and sustaining a career in kidney cancer research (e.g., grant writing, research and laboratory management, publications, professional networking, and committee memberships).
 - To what degree the integration of future FY25 Postdoctoral and Clinical Fellowship Awards into the program supports potential collaborations with Scholars.
- **Patient Advocacy Panel**
 - Whether the application describes the Patient Advocacy Panel and includes the names of at least two patient advocates and at least one Veteran (the Veteran may be one of the patient advocates).
 - To what extent the roles of patient advocates and Veteran(s) on the panel will be integral to the training, networking, and collaboration of the Scholars.
 - Whether the application articulates how the patient advocates and Veteran(s) will have a meaningful role in the AKCI.
 - **Impact**
 - Whether the application describes how the AKCI will bridge the gaps in patient outcomes and care through the multidisciplinary training and support of the next generation of kidney cancer researchers.
 - How well the application justifies the long-term impact of the virtual academy on the future of kidney cancer research.
 - To what extent the [FY24 KCRP Focus Area\(s\)](#) are integrated within the AKCI.

- **Research Strategy and Feasibility**
 - Whether a minimum of three pilot projects has been described.
 - How well the scientific rationale of the pilot projects supports the specific aims.
 - Whether these pilot projects will help launch a career of the Scholars in kidney cancer research.
 - To what degree the pilot projects will represent collaborative efforts by the Academy Leadership and Scholars.
 - How well the application addresses potential problem areas and presents alternative methods and approaches.
 - If applicable, for the proposed research project involving human subjects, whether the application describes the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnic group, and an accompanying rationale for the selection of subject. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement. If women and minorities are excluded, to what extent the application provides a rational justification.
 - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
 - If applicable, whether the application describes how the proposed research using animals meets the regulatory guidelines for appropriateness and robustness of experimental design.
 - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
 - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Data and Resource Sharing**
 - How well the Data and Research Resources Sharing Plan is detailed, including but not limited to:

- The description of the type of data or research resource(s) to be made publicly available.
 - The detailed plan for access to data or research resources.
 - The appropriateness of plans to ensure the data or research resource(s) is/are accessible after the period of performance expires.
 - The appropriateness of the milestones with respect to making the data or research resource(s) available.
 - How well the data in the application follows the FAIR Data Principles for reproducible science found in “[The FAIR Guiding Principles for scientific data management and stewardship.](#)”
- **Budget**
 - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
 - Whether the budget is appropriate for the proposed research.
- **Environment**
 - To what extent the scientific environment is appropriate for the proposed research project.
 - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
 - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **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 priorities of the Defense Health Program and FY24 KCRP, as evidenced by the following:

- **Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:
 - Ratings and evaluations of peer review
 - Adherence to intent of the funding opportunity
 - Program portfolio composition
 - Relevance to at least one of the strategic goals (including “Increase research capacity”)
 - Relative impact and/or military benefit
 - Vision of Academy
- **Stage 2 (Oral Presentation):** During the second stage of programmatic review, the following criteria will be used:
 - Capabilities to lead the Academy such that the Scholars develop partnerships, collaborations, and career growth to ensure their dedication, commitment, and productivity as leading researchers in kidney cancer.
 - Utilization of leadership skills to encourage partnerships, collaborations, resource sharing, and career growth for the Scholars.
 - Evaluation of the proposed milestones and outcomes for the Scholars during the 4 years in the Academy.
 - Justification of proposed kidney cancer pilot research projects that will be conducted as collaborative efforts with the Scholars. With respect to the pilot projects, the metrics used to evaluate the outcomes of the research.
 - The significance of the Patient Advocacy Panel and how it will be integrated into the program.
 - Evaluation of communication strategy/plan to promote the Academy, maximize networking/research collaboration and integrate patients/patient advocacy feedback.

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>.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the KCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

An organizational transfer of an award supporting the Initiating PI or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

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 7, Section F, for general information on organization or PI changes.

II.F.2.a. Pre-Award Meeting

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

II.F.3. 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 cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D Terms and Conditions](#) and the [USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions](#) for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

In-person presentations to the KCRP Programmatic Panel may be requested for this award mechanism.

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.

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 SAM 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 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

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

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

- Failure to submit all associated components (Initiating PI and the Partnering PI) by the application submission deadline.

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 full application:

- An FY24 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, including letters of support/recommendation. *A list of the FY24 KCRP Programmatic Panel members can be found at <https://cdmrp.health.mil/kcrp/panels/panels24>.*
- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- 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.
- A clinical trial is proposed.
- The application fails to address one of the FY24 KCRP Focus Area(s).
- An application for which the named initiating PI (Academy Director) or partnering PI (Academy Deputy Director) does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

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. Full Application Submission Checklist

Full Application Components	Initiating PI Uploaded	Partnering PI Uploaded
SF424 Research & Related Application for Federal Assistance <i>(Extramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
Attachments		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Sample Agenda – Attachment 6, upload as “SampleAgenda.pdf”	<input type="checkbox"/>	
Patient Advocate Panel – Attachment 7, upload as “PatAd.pdf”	<input type="checkbox"/>	
Impact Statement – Attachment 8, upload as “Impact.pdf”	<input type="checkbox"/>	
Animal Research Plan – Attachment 9, upload as AnimalResPlan.pdf		
Representations (<i>Extramural submissions only</i>) – Attachment 10, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form (<i>if applicable</i>) – Attachment 11, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Personal Data		
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Budget (<i>Extramural submissions only</i>)		
Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
Budget (<i>Intramural submissions only</i>)		
Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
Project/Performance Site Location(s) Form		

Research & Related Subaward Budget Attachment(s) Form
(if applicable)

Additional Application Component

Oral Presentation

APPENDIX 1: ACRONYM LIST

AKCILA	Academy of Kidney Cancer Investigators – Leadership Award
ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
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
ET	Eastern Time
FAD	Funding Authorization Document
FAIR	Findable, Accessible, Interoperable, and Reusable
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
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	U.S. Department of Veterans Affairs