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 –

Early-Career Scholar Award

Announcement Type: Initial

Funding Opportunity Number: HT942524KCRPAKCIECSA

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), September 24, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, October 15, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, October 21, 2024
- **Peer Review:** January 2025
- **Programmatic Review:** 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.

- 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 multi-disciplinary 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

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

II.A.3. Award History

The KCRP Academy of Kidney Cancer Investigators – Early-Career Scholar Award mechanism was first offered in FY19. Since then, 26 Academy of Kidney Cancer Investigators – Early-Career Scholar Award applications have been received, and 12 have been recommended for funding.

II.B. Award Information

The Academy of Kidney Cancer Investigators (AKCI) is a virtual research capacity building and research mentoring platform that consists of Early-Career Scholar (ECS)/Designated Mentor pairs from different institutions and an Academy Leadership Team. The KCRP AKCIECSA is not a traditional career development award; the ECS is expected to conduct research, participate in monthly webinars, and annual workshops, and communicate and collaborate with other members of the Academy (other Early-Career Scholars, mentors, Academy Leadership Team) as well as with the kidney cancer advocacy community.

The KCRP Academy of Kidney Cancer Investigators – Early-Career Scholar Award supports a unique, interactive virtual academy providing intensive mentoring, national networking, collaborations, and a peer group for junior faculty emerging as potential leaders of kidney cancer research. The overarching goal of the AKCI is to advance kidney cancer research through development of highly productive kidney cancer researchers in a collaborative research and career development environment.

The Academy Leadership Team, consisting of Academy Director and Deputy Director, serves as a resource for the ECS and mentors, assessing the progress of the ECS and facilitating communication and collaboration among all of the Early-Career Scholars and Designated Mentors, as well as with research and advocacy communities. In addition to fostering ECS scientific development, the AKCI, through its leadership by the Academy Leadership Team, provides professional and leadership development of the ECS to include skills and competencies needed to fund and manage a productive laboratory or research team.

This FY24 program announcement is soliciting Early-Career Scholars and Designated Mentors to join the existing Academy of Kidney Cancer Investigators. This award mechanism enables the ECS (the Scholar named as the Principal Investigator [PI] on the application) to pursue a kidney cancer project that may be basic, translational, and/or clinical research. ***The Designated Mentor is not required to be at the same institution as the ECS.***

The KCRP encourages applications from Early-Career Scholars whose ability to commit to conducting kidney cancer research is limited by minimal resources or a lack of resources, such as a qualified Designated Mentor at their institution, access to kidney cancer research tools, opportunities for establishing collaborations, or other obstacles, which should be identified in the application.

Preliminary data to support the feasibility of the research applications and approaches are required; however, this data does not necessarily need to be derived from the kidney cancer research field.

The ECS must be in the early-career stage. This award provides the ECS with funding, networking and collaborative opportunities, and research experience necessary to develop and sustain a successful, independent career at the forefront of kidney cancer research. This award also provides support and protected time for the ECS for 4 years of intensive research under the guidance of a Designated Mentor experienced in kidney cancer research. Although the AKCI will serve as a conduit to share knowledge and research experience among all Academy members, the ECS and Designated Mentor will be responsible for developing the career development plans of the ECS and for designing and executing the proposed research. ***The ECS must clearly articulate their commitment to a career as a kidney cancer researcher and to participating in and contributing to the growth of the AKCI.***

The Designated Mentor must have a strong record of mentoring and training early-career investigators. With the goal to expand and enrich mentorship capacity within the Academy, a Designated Mentor must agree to also serve as a Secondary Mentor to another ECS in the Academy. The Designated Mentor will be limited to one Primary (applicant ECS/mentor pair) and one Secondary Mentorship. Applicants are not permitted to list the Dean of the Academy as

a Designated Mentor. The ECS and Designated Mentor are required to attend a biennial multi-day Department of Defense (DOD) KCRP AKCI Workshop and, in alternate years, a 1-day DOD KCRP AKCI Workshop.

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 Overarching Strategic Goals and Focus Areas described in Sections II.A.1 and II.A.2, and meets the intent of the AKCIECSA.

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: The 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, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the 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 the American public. 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.

Research involving human subjects and human anatomical substances is permitted; however, 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 grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 KCRP AKCIECSA should not exceed **$725,000**. 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 $2.32M to fund approximately two Academy of Kidney Cancer Investigators – Early-Career Scholar Award applications. 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 funds, which will expire for use on September 30, 2030.

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-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

An investigator may be named on only one Academy of Kidney Cancer Investigators – Early-Career Scholar Award application as a PI.

- Early-Career Scholar
    - Must be less than 5 years from their last postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent as of the full application submission deadline.
        - A Statement of Eligibility is required with the submission of the full application.
    - Individuals in a postdoctoral research position (Ph.D.), clinical fellowship (M.D.), or equivalent, at the time of the full application submission deadline, are not eligible.
    - May be a research- or physician-scientist.
    - Must commit no less than 25% effort to this award for the first 2 years.

- Designated Mentor
    - Must be an independent, established kidney cancer investigator with a record of kidney cancer publications in peer-reviewed journals.
    - May be at the same institution as the ECS.
    - If not at the same institution, another mentor ("Other Mentor," see below) at the ECS's institution must also be included in the application submission.
    - Must demonstrate a commitment (at least 5% effort for mentoring and participating in Academy activities, e.g., offsite meetings and webinars) to develop and sustain the ECS's independent career in kidney cancer research.
    - Mentoring responsibilities include mentoring the ECS (i.e., the PI of this award) and an additional ECS within the Academy.
    - An AKCI Designated Mentor may serve as a Designated Mentor to only one AKCI Early-Career Scholar.
    - The Dean of the Academy may not be listed as a Designated Mentor.
    - Off-site Academy activities include annual in-person workshops and monthly web-based meetings.
- Other Mentor (if applicable)
    - Must be at the same institution as the ECS.
    - Must be an independent researcher, with relevant expertise but not necessarily in kidney cancer.
    - Must show cancer research funding (past and present).

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

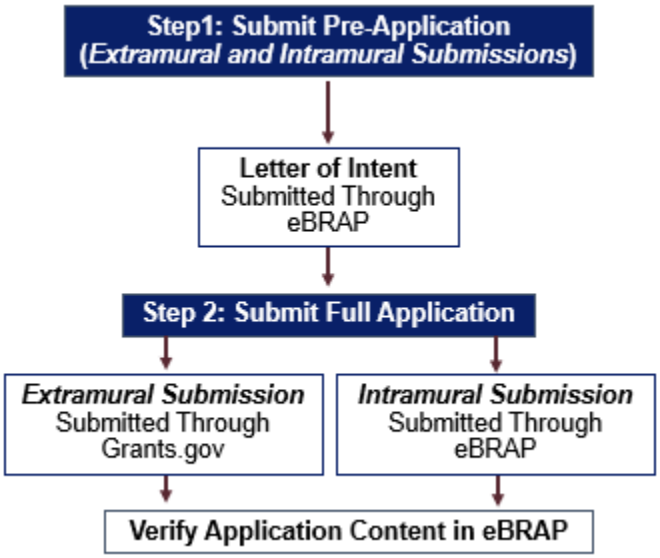
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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

HT942524KCRPAKCIECSA 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 HT942524KCRPAKCIECSA 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 the 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.

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.

  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

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 (11-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.

  - **ECS Career Goals (one-page limit recommended):** Discuss the ECS's record of accomplishments (e.g., awards, honors, first author publications, publications in high-impact journals, presentations/speaking engagements, committees) that demonstrates their potential for becoming an independent investigator in kidney cancer research. Describe the ECS's career goals and plans in kidney cancer research and how the proposed research and career development experience will promote an independent, sustainable career.

  - **Career Development and Sustainment Plan (two-page limit recommended):** Describe the individualized career and professional development plan, which may include workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Explain how this development plan will allow the ECS to obtain independent kidney cancer research funding and to publish in peer-reviewed journals, thereby sustaining an independent career at the forefront of kidney cancer research. Discuss how the Designated Mentor and Other Mentor, if applicable, will assist the ECS in not only developing, but also sustaining, a career as an independent kidney cancer researcher. Explain how the Career Development and Sustainment Plan is supported by the environment; this should include a description of resources available to the ECS at their institution and, if different, at the Designated Mentor's institution. Outline how the ECS and Designated Mentor (and Other Mentor, if applicable) will evaluate the ECS's progress in achieving and sustaining a productive career in kidney cancer research.

  - **Integration of Career Development and Research:** Describe how the individualized career development plan and research project are integrated and how they will contribute to preparing the ECS for an independent, sustainable career in kidney cancer research.

  - **Research Project (seven-page limit recommended):** Concisely present ideas and scientific rationale behind the proposed research. Explain the project's specific aims to be funded by this application. Describe the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls, in sufficient detail for evaluation. Describe the statistical plan including a

power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Preliminary data to support the feasibility of the research and approaches are required; however, these data do not necessarily need to come from the kidney cancer research field. Address potential problem areas and present alternative methods and approaches.

- If animal studies are proposed, applicants should 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 The ARRIVE guidelines 2.0 | ARRIVE Guidelines.

- If the proposed project uses human subjects or human biological samples, include a detailed plan for the recruitment of subjects or the acquisition of samples. The research description should also describe the ability of the ECS to conduct the research or the relevant guidance that will be obtained to accomplish the project.

  - If applicable, describe the strategy for the inclusion of women and minorities in the clinical research 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/or ethnicity, and an accompanying rationale for the selection of subjects. It is not expected that every study will include all genders and racial and ethnic groups. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The Policy on Inclusion of Women and Minorities, and Frequently Asked Questions for the policy may be downloaded from eBRAP under "Resources and Reference Material" at https://ebrap.org/eBRAP/public/Program.htm.

- **Commitment to the AKCI (one-page limit recommended):** Describe why participation in the AKCI is important in developing the Early-Career Scholar's career. Describe the ECS's motivation and commitment to participating in the AKCI, to include opportunities for networking and collaborating with the other ECS/Designated Mentor pairs (if applicable, Other Mentor) and the Academy Leadership Team.

- **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 (two-page limit per letter *is recommended*):** 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)* (one-page limit per letter *is recommended*):** 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 the 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 the CDMRP's expectations for making data and research resources publicly available.

- **Use of DOD Resources *(if applicable)*:** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

  Use of VA Resources *(if applicable)*: Provide a letter of support 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.

- **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.

- **Career Development and Sustainment Plan**
  - Summarize how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the ECS's independent career at the forefront of kidney cancer research.
  - Describe how the proposed research project will allow the PI to make valuable contributions to kidney cancer.
- **Research Plan**
  - Background: Present the ideas and reasoning behind the proposed work.
  - Hypothesis: State the hypothesis to be tested. Provide supporting evidence or rationale.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design, including appropriate controls.
- **Impact**
  - Describe how the proposed research will make an important contribution toward the goal of eliminating kidney cancer.
  - Describe the potential impact of the proposed research on the health and well-being of Service Members, Veterans, and/or the American public who are impacted by this disease.

- **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 hypothesis, supporting evidence, and scientific rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the PI's career goals in kidney cancer research.
    - How do the research and the career development plan support the PI in attaining these goals?

- Describe how the PI will participate in and contribute to the growth of the AKCI.
- Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
- What are the likely contributions of this study to advancing our knowledge of kidney cancer?
- What is the potential impact of the proposed research on the health and well-being of Service Members, Veterans, and/or the American public who are impacted by this disease?

- **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 – Early-Career Scholar Award, refer to the "***Suggested SOW Strategy Generic Research***" document for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Explain how the proposed research and the Career Development and Sustainment Plan will facilitate professional development and sustain the ECS's independent career at the forefront of kidney cancer research. Describe how the proposed research will make an important contribution toward the goal of eliminating kidney cancer that can be readily understood by readers without a background in science or medicine.

- **Attachment 7: Designated Mentor's Letter (three-page limit): Upload as "MentorLetter.pdf".**
  - The Designated Mentor's letter should describe the ECS's background and potential to become an independent kidney cancer researcher. Explain how this award will enhance the ECS's capabilities to sustain a career in kidney cancer research.
  - Describe the Designated Mentor's background and experience in kidney cancer research and record of mentoring and training early-career investigators. Specify the commitment of the Designated Mentor (at least 5% effort) and their staff to the ECS's professional development and career sustainment. Describe the specific resources that will facilitate success for the ECS.

- Explain why the Designated Mentor will be an excellent fit in the Academy irrespective of their accomplishments as a researcher and mentor to other Early-Career Scholars. Describe the Designated Mentor's motivation and commitment to participating in the AKCI with the other ECS/Designated Mentor pairs and the Academy Leadership Team. Describe the Designated Mentor's commitment and time to serve as a Secondary Mentor to another ECS in the AKCI.

- **Attachment 8: Other Mentor's Letter, if applicable (three-page limit): Upload as "OtherMentor.pdf".**

  - The Other Mentor's letter should describe the ECS's background and potential to become an independent kidney cancer researcher. Explain how this award will enhance the ECS's capabilities to sustain a career in kidney cancer research.

  - Describe the Other Mentor's background and experience in research, success in acquiring funding, and record of mentoring and training early-career investigators. Describe the specific resources that will facilitate success for the ECS.

  - Describe the Other Mentor's motivation and commitment to participating in the AKCI with the other ECS/Designated Mentor pairs and the Academy Leadership Team.

- **Attachment 9: Statement of Eligibility (one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official to verify that the eligibility requirements have been met by the application submission deadline. The letter should provide the date (month/year) the PI completed/will complete their most recent postdoctoral position, and the date (month/year) the PI began/will begin their faculty (or equivalent) appointment and research in the proposed setting.

- **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". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

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

(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.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 **4** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$725,000**. 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 maximum allowable funding for the Designated Mentor and the Other Mentor is $30,000 per year in direct costs.

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

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

- Travel costs for the ECS and Designated Mentor (and Other Mentor, if applicable) to attend a biennial DOD KCRP multi-day Academy of Kidney Cancer Investigators Workshop with the KCRP staff, Academy Leadership Team, and other Academy members
- Travel costs for the ECS and Designated Mentor (and Other Mentor, if applicable) to attend a DOD KCRP 1-day AKCI Workshop ***in alternate years*** with the Academy Leadership Team and other Academy members

These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary (ECS, Designated Mentor, Other Mentor, if applicable, and research staff)
- Funding for the Other Mentor (if requested, must be justified)
- Travel costs between collaborating organizations
- Costs associated with participating in required virtual Academy meetings
- Costs for the ECS to travel to two scientific/technical meetings per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results and/or attend workshops as designated in the Career Development Plan of the FY24 KCRP AKCIECSA.

Must not be requested for:

- 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:

- **Early-Career Scholar**

    - The extent to which the ECS's record of accomplishments (e.g., awards, honors, first author publications, publications in high-impact journals, presentations/speaking engagements, committees) demonstrates their potential for becoming an independent investigator in kidney cancer research.

    - The degree to which the ECS's career goals and plans in kidney cancer research and how the proposed research and career development experience are consistent with promoting and sustaining an independent career.

    - How well the Designated Mentor's letter (and, if applicable, Other Mentor's letter) supports the ECS's potential to become an independent kidney cancer researcher and sustain a career in kidney cancer research.

    - The extent to which the ECS is motivated and committed to participating in the AKCI, including networking and collaborating with the other ECS/Designated Mentor pairs and the Academy Leadership Team.

    - The extent to which the AKCI adds value to the ECS's training. Applicant should outline how the AKCI will enhance and complement the ECS's professional growth.

- **Research Strategy and Feasibility**

    - The extent to which the scientific rationale supports the research project and its feasibility as demonstrated by a review and analysis of the literature and relevant preliminary data (preliminary data does not need to come from the kidney cancer research field).

    - The extent to which the experimental design, methods, and analyses, including appropriate randomization, blinding, sample-size estimation, and controls are developed in sufficient detail.

    - To what extent the statistical plan, including a power analysis, demonstrates that the sample size is appropriate to meet the objectives of the study.

    - How well potential problem areas are identified and alternative methods and approaches are addressed.

    - If human subjects or human biological samples are used, how well the plan for recruitment of subjects or the acquisition of samples is detailed.

    - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

    - If applicable, the degree to which the intellectual and material property plan is appropriate.

- 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.

- **Career Development and Sustainment Plan**

  - How well the individualized career and professional development plan, including workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities, is described.

  - How clearly the development plan provides for the ECS to obtain independent kidney cancer research funding and publish in peer-reviewed journals to sustain an independent career.

  - How well the role of the Designated Mentor and Other Mentor (if applicable) in assisting the ECS in developing and also sustaining a career as an independent kidney cancer researcher is discussed.

  - How well the plans for evaluating the ECS's progress of achieving and sustaining a productive career in kidney cancer research are outlined.

  - How well the individualized career development plan and the research project are integrated to contribute to preparing the ECS for an independent, sustainable career in kidney cancer research.

- **Designated Mentor (and, if applicable, Other Mentor)**

  - The extent to which the Designated Mentor's (and, if applicable, Other Mentor's) background and experience in kidney cancer research, success in acquiring funding, and record of mentoring and training early-career investigators are described.

  - How well the Designated Mentor describes their motivation and commitment to participating in the AKCI and why they will be an excellent fit in the Academy irrespective of their accomplishments as a researcher and mentor to other Early-Career Scholars.

  - How well the Designated Mentor's commitment and time to serve as a Secondary Mentor to another ECS in the AKCI is described.

- **Impact**

  - To what extent the proposed research will make an important contribution toward the goal of eliminating kidney cancer.

- **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.

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**:

- **Resources and Environment**
    - The extent to which the proposed research project and career development of the ECS are supported by the availability of facilities, equipment, staff, interaction with research colleagues, and other resources.
    - How well the commitment from the institution (of at least 25% for this award for the first 2 years) supports the career development of the ECS, including time for research and participation in Academy activities such as monthly webinars.
    - The extent to which the specific resources that will facilitate success for the ECS are described.
- **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:
    - Relative impact
    - Program portfolio composition and balance
    - Adherence to the intent of the award mechanism

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

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

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 grants 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 Institutional Animal Care and Use Committee, Institutional Review Board, 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).

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.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than

$10M are required to provide information to 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.
- More than one application is received in which the same Scholar is named as the PI. Only the first application received will be accepted; additional applications will be administratively rejected.

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the 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 ECS does not meet the eligibility criteria.
- The Designated Mentor and/or Other Mentor, if applicable, do not meet the eligibility criteria.
- A clinical trial is proposed.

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	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Designated Mentor's Letter – Attachment 7, upload as "MentorLetter.pdf"	☐
Other Mentor's Letter (*if applicable)* – Attachment 8, upload as "OtherMentor.pdf"	☐
Statement of Eligibility – Attachment 9, upload as "Eligibility.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 10, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 11, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
AKCIECSA	Academy of Kidney Cancer Investigators – Early-Career Scholar Award
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
FY	Fiscal Year
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