

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 Investigator Award**

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-KCRP-AKCIECIA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 14, 2021
- **Application Submission Deadline:** 11:59 p.m. ET, October 5, 2021
- **End of Application Verification Period:** 5:00 p.m. ET, October 7, 2021
- **Peer Review:** November/December 2021
- **Programmatic Review:** February 2022

This program announcement must be read in conjunction with the General Application Instructions, version 605. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the “Package” tab, clicking “Preview,” and then selecting “Download Instructions.”

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2021 (FY21) Kidney Cancer Research Program (KCRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP). The KCRP was initiated in 2017 to provide support for research of exceptional scientific merit in the area of kidney cancer. Appropriations for the KCRP from FY17 through FY20 totaled \$85 million (M). The FY21 appropriation is \$50M.

II.A.1. KCRP Overarching Strategic Goals

The KCRP's vision is to eliminate kidney cancer through collaboration and discovery. The mission of the FY21 KCRP is to promote rigorous, innovative, high-impact research in kidney cancer for the benefit of Service Members, Veterans, and the American public. Within this context, the KCRP is interested in supporting research and clinical care that addresses the KCRP Overarching Strategic Goals to: (1) increase understanding of the biology of kidney cancer; (2) develop novel therapeutic strategies for the treatment of kidney cancer; (3) improve patient care for kidney cancer; and (4) grow the field and increase collaboration in the area of kidney cancer.

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

II.A.2. FY21 KCRP Focus Areas (*New for FY21*)

Academy of Kidney Cancer Investigators – Early-Career Investigator Award applications must address at least one of the FY21 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, accurate diagnosis and prognosis prediction of kidney cancers, with examples including biomarkers and imaging.
- Define the biology of rare kidney cancers and develop treatments to improve outcomes and reduce death.
- Develop novel therapeutic strategies for the treatment of kidney cancer, such as novel drug targets, therapeutic modalities and agents, treatment combinations and drug delivery systems.

- Identify and implement strategies to improve the quality of life of patients.
- Identify and implement strategies to mitigate health disparities, such as access to healthcare, social and cultural factors, environmental factors, and biological contributors.

Disease Subtype: Applicants are encouraged to select the kidney cancer subtype that the study seeks to address.

- Clear Cell Renal Cell Carcinoma (ccRCC)
- Papillary RCC
- Chromophobe RCC
- Collecting duct carcinoma
- Translocation RCC
- Renal medullary carcinoma (RMC)
- Transitional cell carcinoma (TCC)
- Wilms tumor (nephroblastoma)
- Renal sarcoma
- Angiomyolipoma
- Oncocytoma
- Unclassified/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 Investigator Award mechanism was first offered in FY19. Since then, 11 Kidney Cancer Investigators – Early-Career Investigator Award applications have been received, and 6 have been recommended for funding.

II.B. Award Information

The KCRP Academy of Kidney Cancer Investigators Awards support 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 Academy of Kidney Cancer Investigators (AKCI) is to develop

successful, highly productive kidney cancer researchers in a collaborative research and career development environment.

The AKCI is a virtual career development and research training platform that consists of Early-Career Investigator (ECI)/Designated Mentor pairs from different institutions, and an Academy Dean. The KCRP AKCIECIA is not a traditional career development award; the ECI is expected to participate in monthly webinars and annual workshops and to communicate and collaborate with other members of the Academy (other ECIs, mentors, Dean) as well as with the kidney cancer advocacy community.

The Academy Dean, selected in FY19, serves as a resource for the ECIs and mentors, assessing the progress of the ECIs, and facilitating communication and collaboration among all of the ECIs and mentors, as well as with research and advocacy communities. In addition to fostering ECI scientific development, the AKCI, through its leadership by the Academy Dean, provides professional and leadership development of the ECIs to include skills and competencies needed to fund and manage a productive laboratory or research team.

This FY21 program announcement is soliciting ECIs and Designated Mentors to join the newly established Academy. This award mechanism enables the ECI (the investigator 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 ECI.***

The KCRP encourages applications from ECIs 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 ECI must be in the early-career stage. This award provides the ECI 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 ECI 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 ECI and Designated Mentor will be responsible for developing the ECI's career development plans and for designing and executing the proposed research. ***The ECI 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 ECI in the

Academy. The Designated Mentor will be limited to one Primary (applicant ECI-mentor pair) and one Secondary mentorship. The Dean of the Academy cannot be listed as a Designated Mentor. The ECI 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.

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

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the DOD during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

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 FY21 KCRP priorities.

Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military families, and the American public.

The anticipated direct costs budgeted for the entire period of performance for an FY21 AKCIECIA will not exceed **\$725,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2022. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$3.48M to fund approximately three AKCIECIA Award applications. Funding of applications received is contingent upon the availability of

federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trials are not allowed. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military patient populations and/or DOD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Research Involving Animals: All DOD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and federal government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this program announcement may be submitted by extramural and intramural organizations, these terms are defined below.

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

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

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Each investigator may be named on only one KCRP AKCIECIA application as a PI.

- Early-Career Investigator
 - Must be less than 3 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 full application submission deadline are not eligible.
 - May be a research- or physician-scientist.
 - Must not have a concurrent career development-like award at the time of this award.
 - 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 ECI.
 - If not at the same institution, another mentor (“Other Mentor,” see below) at the ECI’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 – offsite meetings and webinars) to develop and sustain the ECI’s independent career in kidney cancer research.
 - Mentoring responsibilities include mentoring the ECI (i.e., the PI of this award) and an additional ECI within the Academy.
 - An AKCI Designated Mentor may serve as a Designated Mentor to only one AKCI-ECI.
 - 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 ECI.
 - 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.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

II.D. Application and Submission Information

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

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DOD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org

Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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

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

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the

entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org>).

The applicant organization and associated PI [and mentor(s)] identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://ebrap.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY21 KCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

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

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this program announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the **same version** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

Table 1. Full Application Submission Guidelines

| Extramural Submissions | Intramural DOD Submissions |
|--|--|
| Application Package Location | |
| Download application package components for W81XWH-21-KCRP-AKCIECIA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission. | Download application package components for W81XWH-21-KCRP-AKCIECIA from eBRAP (https://ebrap.org). |
| Full Application Package Components | |
| SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information. | <p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p> |
| <p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget | <p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget |

| Extramural Submissions | Intramural DOD Submissions |
|---|--|
| <ul style="list-style-type: none"> • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable) | <ul style="list-style-type: none"> • Performance Sites <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p> |
| Application Package Submission | |
| <p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p> | <p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p> |
| <u>Application Verification Period</u> | |
| <p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p> | <p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into</p> |

| Extramural Submissions | Intramural DOD Submissions |
|---|---|
| | eBRAP to review and to approve prior to the application verification deadline. |
| Further Information | |
| <p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p> | <p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p> |

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

- **Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application package may not exceed 200 MB.

- **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 that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **ECI’s Career Goals (one-page limit recommended):** Discuss the ECI’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 ECI’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 (one-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 ECI to obtain independent kidney cancer research funding and 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 ECI 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 ECI at their institution and, if different, at the Designated Mentor’s institution. Outline how the ECI and Designated Mentor (and Other Mentor, if applicable) will evaluate the ECI’s progress of achieving and sustaining a productive 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 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 ECI 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>.

- **Integration of Career Development and Research (one-page limit recommended):** Describe how the individualized career development plan and research project are integrated and how they will contribute to preparing the ECI for an independent, sustainable career in kidney cancer research.
- **Commitment to the AKCI (one-page limit recommended):** Describe why participation in the AKCI is important in developing the ECI’s career. Describe the ECI’s motivation and commitment to participating in the AKCI, to include opportunities for networking and collaborating with the other ECI/Designated Mentor pairs (if applicable, Other Mentor) and the Academy Dean.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support (two-page limit per letter 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. **The institution must demonstrate a commitment to the ECI through:**
 - No less than 25% effort committed to this award for the first 2 years.
 - Describe what, if any, institutional support (e.g., supplies, staff, salary, start-up package) may be provided for up to 4 years of the AKCIECIA by the institution.
 - Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- **Intellectual Property:** Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Use of DOD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.
- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

Programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. Technical abstracts should be written using the outline below:

- **Career Development and Sustainment Plan**

- Summarize how the proposed research and Career Development and Sustainment Plan will facilitate and sustain the ECI’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, retirees, their family members, and all civilians impacted by this disease.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community. ***Do not duplicate the technical abstract.*** Lay abstracts should be written using the outline below:

- 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 does the research and 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, retirees, their family members, and all individuals impacted by this disease?
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the AKCIECIA mechanism, refer to the “***Suggested SOW Strategy Generic Research***” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
 - Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
 - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
 - Identify cell line(s) and commercial or organizational source(s) to be used.
 - If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other government agency.
- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** Explain how the proposed research and Career Development and Sustainment Plan will facilitate professional development and sustain the ECI’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.
 - **Attachment 7: Inclusion of Women and Minorities Inclusion Enrollment Report format: Upload as “IWAM.pdf”.** If applicable, provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The suggested Inclusion Enrollment Report format, 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>.
 - **Attachment 8: Designated Mentor’s Letter (three-page limit): Upload as “MentorLetter.pdf”.**
 - The Designated Mentor’s letter should describe the ECI’s background and potential to become an independent kidney cancer researcher. Explain how this award will enhance the ECI’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 ECI’s professional development and career sustainment. Describe the specific resources that will facilitate success for the ECI.

- Explain why the Designated Mentor will be a “great” fit in the Academy irrespective of their accomplishments as a researcher and mentor to other ECIs. Describe the Designated Mentor’s motivation and commitment to participating in the AKCI with the other ECI/Designated Mentor pairs and the Academy Dean. Describe the Designated Mentor’s commitment and time to serve as a secondary mentor to another ECI in the AKCI.
- **Attachment 9: Other Mentor’s Letter, if applicable (three-page limit): Upload as “OtherMentor.pdf”.**
 - The Other Mentor’s letter should describe the ECI’s background and potential to become an independent kidney cancer researcher. Explain how this award will enhance the ECI’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 ECI.
 - Describe the Other Mentor’s motivation and commitment to participating in the AKCI with the other ECI/Designated Mentor pairs and the Academy Dean.
- **Attachment 10: 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 11: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.
- **Attachment 12: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] et seq.), the DOD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.
 - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf”.
 - Include the Designated Mentor’s biographical sketch.
 - Include Other Mentor’s biographical sketch, if applicable.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.
 - Include Designated Mentor’s previous/current/pending support.
 - Include Other Mentor’s previous/current/pending support, if applicable.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 11](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the federal awarding agency is ready to make a federal award, the federal awarding agency may determine that the applicant is not qualified to receive a federal award and use that determination as a basis for making a federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General

Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **4** years.

The anticipated direct costs budgeted for the entire period of performance will 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. No budget will be approved by the government exceeding **\$725,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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

- Travel costs for the ECI and Designated Mentor (and Other Mentor, if applicable) to attend an annual DOD KCRP 1-day AKCI Workshop with the Academy Dean and other Academy members
- Travel costs for the ECI 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 Dean, 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 (ECI, Designated Mentor, Other Mentor, if applicable, and research staff)
- Maximum allowable funding for the Designated Mentor is \$30,000 per year in direct costs
- Funding for the Other Mentor (if requested, must be justified)
- Travel costs between collaborating organizations
- Costs associated with participating in the virtual Academy (e.g., hardware and/or software for the audio- or video-teleconferencing or web-based communications)
- Costs for one investigator to travel to two scientific/technical meetings per year in addition to the required meetings described above. 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 FY21 KCRP AKCIECIA.

Must not be requested for:

- Tuition

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DOD or other federal agency is not allowed except under very limited circumstances. Funding to intramural DOD and other federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Early-Career Investigator**
 - The extent to which the ECI'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 ECI'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 ECI's potential to become an independent kidney cancer researcher and sustain a career in kidney cancer research.
 - The extent to which the ECI is motivated and committed to participating in the AKCI, including networking and collaborating with the other ECI/Designated Mentor pairs and the Academy Dean.

- **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.

- **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 ECI 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 ECI in developing and also sustaining a career as an independent kidney cancer researcher is discussed.
- The extent to which the Career Development and Sustainment Plan is supported by the environment, including the description of resources available to the ECI.
- How well the plans for evaluating the ECI'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 ECI 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 is described.
 - The extent to which the specific resources that will facilitate success for the ECI are described.
 - How well the Designated Mentor describes their motivation and commitment to participating in the AKCI and why they will be a “great” fit in the Academy irrespective of their accomplishments as a researcher and mentor to other ECIs.
 - How well the Designated Mentor’s commitment and time to serve as a secondary mentor to another ECI in the AKCI is described.

- **Impact**
 - To what extent the proposed research makes an important contribution toward the goal of eliminating kidney cancer.

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

- **Resources and Environment**
 - The extent to which the proposed research project and career development of the ECI 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 ECI, including time for research and participation in Academy activities such as monthly webinars.
 - If applicable, the degree to which the intellectual and material property plan is appropriate.

- **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.

- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the FY21 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.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the KCRP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the

federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a federal awarding agency previously entered and is currently available in FAPIIS.

The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

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

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY21 funds are anticipated to be made no later than September 30, 2022. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds. No commitment on the part of the government should be inferred from discussions with any other individual. **The award document signed by the Grants Officer is the official authorizing document.**

Federal Government Organizations: Funding made to federal government organizations (to include intramural DOD organizations) will be executed through the Military Interdepartmental

Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

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

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

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

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [USAMRAA General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

The Award Terms and Conditions will specify if 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 if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Inclusion Enrollment Reporting Requirement (*only required for clinical research studies*): Enrollment on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final technical report. The suggested Inclusion Enrollment Report format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP.

Awards resulting from this program announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to program announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the program announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 605a. The program announcement numeric version code will match the General Application Instructions version code 605.

II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- More than one application is received in which the same investigator 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 application:

- An FY21 KCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including,

but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY21 KCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/kcrp/panels/panels21>.*

- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The ECI 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. Application Submission Checklist

| Application Components | Action | Completed |
|--|--|-----------|
| SF424 Research & Related Application for Federal Assistance (extramural submissions only) | Complete form as instructed | |
| Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only) | Complete tabs as instructed | |
| Attachments | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf" | |
| | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf" | |
| | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf" | |
| | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf" | |
| | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf" | |
| | Impact Statement: Upload as Attachment 6 with file name "Impact.pdf" | |
| | Inclusion of Women and Minorities Inclusion Enrollment Report format: Upload as Attachment 7 with file name "IWAM.pdf". | |
| | Designated Mentor's Letter: Upload as Attachment 8 with file name "MentorLetter.pdf" | |
| | Other Mentor's Letter: Upload as Attachment 9 with file name "OtherMentor.pdf" if applicable | |
| | Statement of Eligibility: Upload as Attachment 10 with file name "Eligibility.pdf" | |
| | Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf" if applicable | |
| | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable | |
| Research & Related Personal Data | Complete form as instructed | |

| Application Components | Action | Completed |
|--|--|-----------|
| Research & Related Senior/Key Person Profile (Expanded) | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field | |
| | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field | |
| | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field | |
| | Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field | |
| Research & Related Budget (extramural submissions only) | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field | |
| Budget (intramural submissions only) | Suggested DOD Military Budget Format, including justification | |
| Project/Performance Site Location(s) Form | Complete form as instructed | |
| Research & Related Subaward Budget Attachment(s) Form, if applicable | Complete form as instructed | |

APPENDIX 1: ACRONYM LIST

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|----------|--|
| ACURO | Animal Care and Use Review Office |
| AKCI | Academy of Kidney Cancer Investigators |
| AKCIECIA | Academy of Kidney Cancer Investigators – Early-Career Investigator Award |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| DOD | Department of Defense |
| DoDGARs | Department of Defense Grant and Agreement Regulations |
| DUNS | Data Universal Numbering System |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| ECI | Early-Career Investigator |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FAPIIS | Federal Awardee Performance and Integrity Information System |
| FY | Fiscal Year |
| HRPO | Human Research Protection Office |
| IACUC | Institutional Animal Care and Use Committee |
| IRB | Institutional Review Board |
| KCRP | Kidney Cancer Research Program |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NIH | National Institutes of Health |
| ORCID | Open Researcher and Contributor ID, Inc. |
| ORP | Office of Research Protections |
| PI | Principal Investigator |
| RDT&E | Research, Development, Test, and Evaluation |
| SAM | System for Award Management |
| SOW | Statement of Work |
| STEM | Science, Technology, Engineering, and/or Mathematics |
| UEI | Unique Entity Identifier |
| URL | Uniform Resource Locator |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC | United States Code |
| VA | Department of Veterans Affairs |