

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

Idea Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524KCRPIDA

**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:** December/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 FY24 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 Idea Development Award mechanism was first offered in FY17. Since then, 520 Idea Development Award applications have been received, and 104 have been recommended for funding.

II.B. Award Information

The FY24 KCRP Idea Development Award is intended to support innovative ideas and high-impact approaches, based on scientifically sound evidence, to move toward the KCRP vision of eliminating kidney cancer. The research project should include a well-formulated, testable hypothesis based on strong scientific rationale and a well-developed and articulated research approach. Personnel on the proposed team should have a strong background in kidney cancer research.

The following are significant features of this award mechanism:

Research Approach: The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of kidney cancer. Experimental strategies may be novel or may be based on strong rationale derived from previously published data and/or presented preliminary data. The feasibility of the research design and methods should be well-defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved. Additionally, resources should be identified, and availability supported through documentation. Identification of potential problems and pitfalls with alternate approaches should be addressed. A statistical analysis plan for the proposed research should be included, if applicable, as well as a power analysis to support the design and sample size.

Preliminary Data: *Preliminary data are required* but need not be in kidney cancer. Preliminary data may include unpublished or published results from the laboratory of the Principal Investigator (PI) or collaborators named on the application and/or data from the published literature relevant to kidney cancer.

Innovation: Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. This may include high-risk, potentially high-gain, approaches to kidney cancer research, provided the application demonstrates the potential for significant impact on the field of research, patient care, and/or quality of life. Research that is likely to yield only an incremental advance is not considered innovative.

Impact: Proposed research projects should address a central critical issue or question in kidney cancer research or clinical care. High-impact research will, if successful, significantly advance current methods and concepts in at least one of the [FY24 KCRP Focus Areas](#).

Personnel: Personnel are considered a crucial element of the FY24 KCRP Idea Development Award. The application should demonstrate the investigators' experience in kidney cancer through the PI's background, the research team, and/or through collaboration. Collaborations should be documented.

The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under the current program announcement:

- **All Applications:** Innovative, high-risk/high-reward and/or preclinical research that is supported by preliminary and/or published data.

Partnering PI Option: The FY24 KCRP supports collaborative research to bring a new perspective to kidney cancer research and/or facilitate progress in the field by combined efforts. Therefore, the KCRP Idea Development Award mechanism includes a Partnering PI Option, which is structured so that two investigators, each of whom will be designated as a PI and receive a separate award, will work synergistically on a single project. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should collaborate to develop a synergistic project addressing one or more of the FY24 KCRP Idea Development Award Focus Areas. Applications *submitted by a mentor*

and trainee as Initiating PI and Partnering PI do not meet the intent of the Partnering PI Option. Multidisciplinary and multi-organizational projects are allowed. Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); however, both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. It should be clear that both investigators have had an equal level of intellectual input and effort in developing the application. If recommended for funding, each PI will be named to an individual award within the recipient organization.

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 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](#).

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 and addresses the FY24 KCRP strategic goals and focus areas described in [Section II.A.1](#) and [Section II.A.2](#).

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

Women's Health: 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 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.

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 IDA should not exceed **\$800,000**. The anticipated combined direct costs budgeted for the entire period of performance for an FY24 KCRP Idea Development Award – Partnering PI Option will not exceed **\$1.2M**. 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 \$18.56M to fund approximately 13 Idea Development 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-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

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

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

II.C.1.b. Principal Investigator

Investigators at or above the level of Assistant Professor (or equivalent) may be named by the organization as the PI on the application.

There are no limits on the number of applications for which an investigator may be named as a PI for this Idea Development Award program announcement.

However, investigators are discouraged from being named on multiple applications unless they are clearly addressing distinct research questions. Applications will be required to include a brief description of all applications in which the PI is named as a PI or collaborator under this Idea Development Award program announcement.

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.

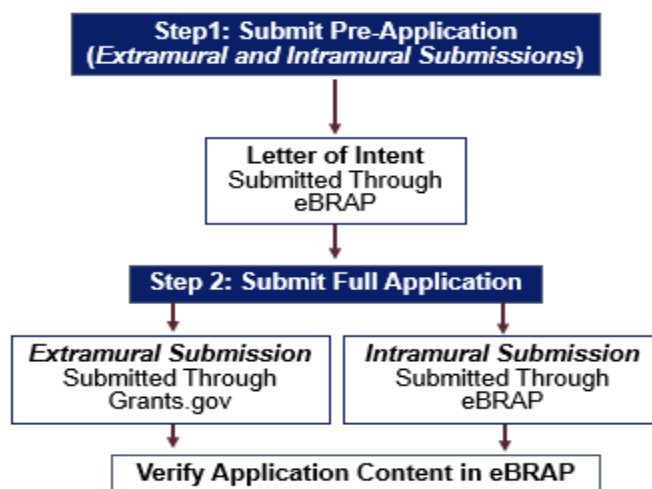
The CDMRP uses two portal systems to accept pre- and full application submissions.

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 HT942524KCRPIDA 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 HT942524KCRPIDA 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

All pre-application components must be submitted by the PI or, *if exercising the Partnering PI Option*, the Initiating PI, through eBRAP (<https://eBRAP.org/>), including the submission of contact information for the Partnering PI.

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

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Instead, the Partnering PI must follow the link in the notification email to ASSOCIATE the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

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

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

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

When starting the pre-application, applicants will be asked to select a “Mechanism Option”. Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Idea Development Award- Single PI	IDA
Idea Development Award- Partnering PI Option	IDA – PPIO

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

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research. Describe previous experience most pertinent to the application. Preliminary data are required but need not be in kidney cancer research. State the [FY24 KCRP Focus Area\(s\)](#) to be addressed.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If this research project is part of a larger study, present only the tasks that this award would fund.
- **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources such as tissue, data, or human subjects (if applicable). Provide the scientific rationale that supports the project and its feasibility through a critical review and analysis of the literature, preliminary data, and/or logical reasoning. Address potential problem areas and present alternative methods and approaches. If applicable, describe the statistical plan with appropriate power analysis and how it supports the sample size.

Research projects may include preclinical studies in animal models or in human subjects and/or human anatomical substances.

- 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 human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI and/or collaborators in recruiting human subjects for similar projects. ***This award may not be used to conduct clinical trials.***
 - ❖ 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>.
- **Personnel:** Explain the degree to which the proposed research demonstrates a critical understanding and in-depth knowledge of kidney cancer.

Note: Impact and Innovation should be addressed in [Attachment 6](#) and [Attachment 7](#), respectively, not in the Project Narrative (Attachment 1).

- **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 (one-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.

- **Background:** Present the ideas and reasoning behind the proposed research.
- **Focus Areas:** State the [FY24 KCRP Focus Area\(s\)](#) to be addressed.
- **Hypothesis/Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Briefly describe the study design, including the appropriate controls.
- **Impact:** Describe how the proposed research is relevant to at least one of the [FY24 KCRP Focus Areas](#).
- **Innovation:** Briefly describe the novelty or paradigm shift proposed in the project and how it will yield critical discoveries, new avenues of investigation, or major advancements to prevent or cure kidney cancer.
- **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 scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
- State the [FY24 KCRP Focus Area\(s\)](#) to be addressed.
- 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? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field. What is the projected time it may take to achieve a clinically relevant outcome? What are the likely contributions of this study to advancing the field of cancer research and/or patient care? Describe the impact that the proposed research project results might have on the field of kidney cancer research and/or patient care in the short term and/or long term for Service Members, their Families, Veterans, and the American public.
- Describe the innovative aspects of the proposed research project.
- **Attachment 5: Statement of Work (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 Idea Development Award, refer to either the “Assembling a Generic Statement of Work”, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

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

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.** The Impact Statement should be written to be written in lay language so that it can be readily understood by readers without a background in science or medicine.
 - Describe how the proposed research is relevant to at least one of the [FY24 KCRP Focus Areas](#) in a way that is consistent with the program’s goals.
 - Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will directly result from the proposed research to drive the kidney cancer field forward and support new avenues for research or clinical care.
 - Describe the long-term impact: Explain the potential long-term impact of this study on the field of kidney cancer research and/or patient care.
 - Describe how the proposed research will, whether in the short term or long term, lead to an original and important contribution toward advancing basic, translational, or clinical kidney cancer research, or on the quality of life of individuals with kidney cancer.
- **Attachment 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.**
 - Summarize how the proposed work is innovative.
 - Describe how the proposed research project introduces a new paradigm or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.
 - Describe how the research represents more than an incremental advance on the data provided or current work in the applicant’s laboratory.
 - Explain how the potential level of gain for the research community or patient community justifies the risk of the proposed research project.
- **Attachment 8: Public Health Service (PHS) Inclusion Enrollment Report, if applicable: Upload as “PHS.pdf”.** If applicable, provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race are exempt from this requirement. The PHS Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

- **Attachment 9: Submissions Statement (one-page limit): Upload as “Submissions.pdf”.** *(Attachment 9 is only applicable and required for applications in which the Initiating PI and/or Partnering PI is named in multiple FY24 KCRP Idea Development Award applications. The Initiating PI is responsible for submitting Attachment 9. This attachment will be available for programmatic review only.)*

Provide the following information for each individual named as a PI or collaborator in multiple Idea Development Award applications:

- CDMRP Log Number, funding option, role on the project, project title, and specific aims.
- Brief description of how the application addresses a research question that is distinct from the other application(s).

- **Attachment 10: Animal Research Plan (three-page limit): Upload as “AnimalResPlan.pdf”.** *(Attachment 10 is only applicable and required for applications proposing animal studies.)*

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

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 11: 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 12: 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.

- **Partnering PI Option:** *Initiating and Partnering PIs must **each** have a separate budget and justification **specific to their distinct portions of the effort** that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should **not** include budget information for Partnering PI(s) even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

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

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

II.D.2.b.iii. Full Application Submission Components for the Partnering PI

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

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

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf”. Each PI must submit an *identical* copy of a jointly created SOW.
- **Attachment 11: Representations (Extramural submissions only):** Upload as “RequiredReps.pdf”.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form:** Upload as “IGBudget.pdf”.

- (c) **Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.
- (d) **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”.
 - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
- (e) **Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.
- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf”.
 - *The Initiating PI and Partnering PI must **each** submit a budget and justification **specific to their own portion of the efforts** as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should **not** include budget information for the Initiating PI, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.*
- (f) **Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.
- (g) **Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed information.
- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
 - **Intramural DOD Subaward:** Complete the “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 12.

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

Single PI Option:

The maximum period of performance is 4 years.

The application’s direct costs budgeted for the entire period of performance should not exceed **\$800,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 4 years.

Partnering PI Option:

The maximum period of performance is 4 years.

The application's combined direct costs budgeted for the entire period of performance should not exceed \$1.2M. 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.

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

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

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 4 years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator (or for the Partnering PI Option: one investigator from each partnering application) to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 KCRP Idea Development Award.
- Research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

For this award mechanism, direct costs must not be requested for:

- Clinical trial costs

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 of equal importance:

- **Research Strategy and Feasibility**

- To what degree the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, preliminary data, and/or logical reasoning.
- To what degree the proposed research demonstrates a critical understanding and in-depth analysis of kidney cancer.
- How well the hypotheses or objectives, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
- To what degree the research design and methods can successfully achieve the goals of the proposed project.
- To what extent the application identifies potential problems and addresses alternative approaches.
- Whether the application includes an appropriate statistical plan with power analysis, if applicable. How well the described statistical plan will evaluate the results and if it is appropriate for the sample size according to the power analysis.
- Whether the application demonstrates the availability of resources such as tissue, data, or human subjects, if applicable.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- 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.

- **Innovation**

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies,

adaptations of existing methods or technologies, or looks at existing problems or issues from a new perspective.

- To what degree the potential level of gain for the research community or patient community justifies the risk of the proposed research project.
- To what extent the proposed research represents more than an incremental advance upon the data provided or current research being performed in the applicant's laboratory.

- **Impact**

- Whether the application addresses at least one of the [FY24 KCRP Focus Areas](#).
- To what extent the proposed research will, whether in the short term or long term, lead to an original and important contribution toward advancing basic, translational, or clinical kidney cancer research, or on the quality of life of individuals with kidney cancer.
- To what degree the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) will drive the kidney cancer field forward and support new avenues for research or clinical care.
- How well the anticipated long-term gains from this research will yield relevant results for kidney cancer research or patient care.

- **Personnel**

- To what degree the research team's qualifications and experience/expertise and each individual's specific contributions, including how the appropriate experience is incorporated, address the research question and enable the success of the proposed project.
- How appropriate the levels of effort are for successful conduct of the proposed work.
- **Partnering PI Option:** How the partners' combined expertise will better address the research question.

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**:

- **Budget**

- Whether the direct costs exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research.

- **Environment**

- To what extent the scientific environment is appropriate for the proposed research project.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources.
- To what extent the quality and level of institutional support are appropriate for the proposed research project.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **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:
 - Adherence to the intent of the award mechanism
 - Programmatic relevance to [FY24 KCRP Focus Areas](#)
 - Relative impact and innovation

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

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

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

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

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

II.F.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.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

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

Email: support@grants.gov

II.H. Other Information

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

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

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

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the full application:

- An FY24 KCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 KCRP Programmatic Panel members can be found at <https://cdmrp.health.mil/kcrp/panels/panels24>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI does not meet the eligibility criteria.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI or Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance (<i>Extramural submissions only</i>)	<input type="checkbox"/>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) (<i>Intramural submissions only</i>)	<input type="checkbox"/>	<input type="checkbox"/>
Attachments		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
Innovation Statement – Attachment 7, upload as “Innovation.pdf”		
Public Health Service Inclusion Enrollment Report (<i>if applicable</i>) – Attachment 8, upload as “PHS.pdf”	<input type="checkbox"/>	
Submissions Statement (<i>if applicable</i>) – Attachment 9, upload as “Submissions.pdf”	<input type="checkbox"/>	
Animal Research Plan – Attachment 10, upload as AnimalResPlan.pdf	<input type="checkbox"/>	
Representations (<i>Extramural submissions only</i>) – Attachment 11, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental Budget Form (<i>if applicable</i>) – Attachment 12, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Budget (<i>Extramural submissions only</i>) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>

Full Application Components	Uploaded	
	PI or Initiating PI	Partnering PI
Budget (<i>Intramural submissions only</i>) Include budget justification	<input type="checkbox"/>	<input type="checkbox"/>
Project/Performance Site Location(s) Form	<input type="checkbox"/>	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form (<i>if applicable</i>)	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ARRIVE	Animal Research: Reporting <i>In Vivo</i> Experiments
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IDA	Idea Development Award
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs