

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Kidney Cancer Research Award

Postdoctoral and Clinical Fellowship Award

Announcement Type: Initial

Funding Opportunity Number: HT942524KCRPPCFA

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent Submission Deadline: 5:00 p.m. Eastern time (ET), August 15, 2024**
- **Confidential Letters of Recommendation Submission Deadline: 5:00 p.m. ET, September 5, 2024**
- **Application Submission Deadline: 11:59 p.m. ET, September 5, 2024**
- **End of Application Verification Period: 5:00 p.m. ET, September 10, 2024**
- **Peer Review: December 2024**
- **Programmatic Review: January 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

II.A.3. Award History

The KCRP Postdoctoral and Clinical Fellowship Award was first offered in FY20. Since then, 48 Postdoctoral and Clinical Fellowship Award applications have been received, and 22 have been recommended for funding.

II.B. Award Information

The FY24 KCRP Postdoctoral and Clinical Fellowship Award supports recent doctoral or medical school graduates in pursuit of innovative, high-impact kidney cancer research during their postdoctoral and/or clinical fellowship and allows them to obtain the necessary experience for an independent career as a leader in kidney cancer research. Applicants must demonstrate that the proposed research has high potential to lead to, or make, significant advancements in kidney cancer research and/or patient care. Applicants for this award must also exhibit a strong desire to pursue a career in kidney cancer research, with clear evidence for a researcher development plan that will lead to a successful independent career in kidney cancer.

The critical components of this award mechanism are:

Impact: Research supported by the FY24 KCRP Postdoctoral and Clinical Fellowship Award will have the potential for a major impact and accelerate progress toward ending kidney cancer. The impact may be short term or long term, but must move beyond an incremental advance. Applications are expected to identify the kidney cancer patients or at-risk individuals who would ultimately benefit from the proposed research.

Research Strategy: The research proposed as part of the Postdoctoral and Clinical Fellowship Award must have high potential to lead to or make breakthroughs in kidney cancer. The scope of the research may include innovative, high-risk/high-reward research in the early stages of idea development or research already supported by preliminary data with the potential to make significant advancements toward clinical translation. The research strategy should demonstrate sound rationale, logical reasoning, and, if available, preliminary data. The proposed research should show evidence of rigorous experimental design, sufficient experimental details, appropriate controls, a statistical plan, and consideration of pitfalls and alternatives.

Principal Investigator (PI): Under this award mechanism, the postdoctoral or clinical fellow is considered the PI and, as such, is expected to write the project narrative, researcher development plan, and other application components, with appropriate guidance from the mentor. *While the PI is not required to have previous experience in kidney cancer research, the proposed project and researcher development plan must focus on kidney cancer.* Applications must emphasize the PI's potential for success in becoming an independent kidney cancer researcher based on their qualifications, achievements/honors (including first-author publications and funding), and letters of recommendation.

Mentor: The mentor (or co-mentor, if applicable) must possess the appropriate experience in kidney cancer research and/or patient care, to include recent publications and a record of active funding, and clearly demonstrate a commitment to guiding the PI's research and development as a researcher. If the mentor is not an experienced kidney cancer researcher, then formal co-mentorship by an established kidney cancer researcher is required. The application must include information about the mentor's experience in conducting innovative research and how they intend to support the PI's endeavors in kidney cancer. Mentorship by an investigator without an established record of mentoring pre- and/or postdoctoral trainees may be offset by the overall strength of the researcher development plan.

Researcher Development Plan: Applications must provide details on the suitability of the PI's overall researcher development plan for attaining the goals of this award mechanism. Applications must elaborate on the qualities of the research environment in which the candidate will work, provide details on the *individualized kidney cancer-focused researcher development plan*, and describe how it will facilitate the PI's career development as an independent, innovative kidney cancer researcher. A multidisciplinary research approach to kidney cancer is highly encouraged, but not required; however, if there are multidisciplinary aspects, they should be clearly outlined in the application.

Organizational-Level Emphasis:

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

Nuclear Medicine: Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and

targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

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

Metastatic Cancer Task Force: A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 KCRP priorities.

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

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

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this program announcement.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does **not** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do **not** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under [§46.104\(d\)\(4\) of the Common Rule](#).

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 KCRP Postdoctoral and Clinical Fellowship Award should not exceed **\$195,000**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

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

The CDMRP expects to allot approximately \$2.18M to fund approximately seven Postdoctoral and Clinical Fellowship 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

As of the full-application submission deadline:

- Postdoctoral PIs must have successfully completed, by March 6, 2025, the requirements for a doctoral and/or medical degree.
- All eligible PIs must be in the laboratory or clinical research setting in which the proposed research is to be performed as a postdoctoral or clinical fellow.
- All eligible PIs must have 4 years or less of postdoctoral and/or mentored clinical research training experience (excluding family medical leave).

Each investigator may be named on only one KCRP Postdoctoral and Clinical Fellowship Award application as a PI.

Only postdoctoral and/or clinical fellows are eligible. Faculty members and all other non-postdoctoral and clinical fellow positions are not eligible.

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

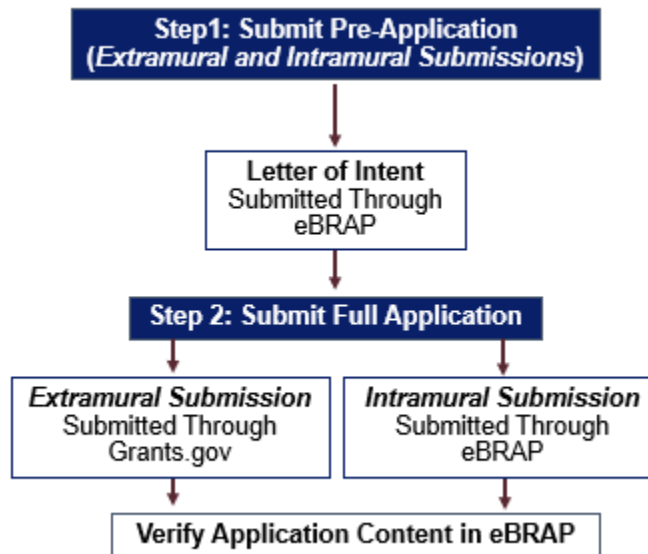
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission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

HT942524KCRPPCFA 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 HT942524KCRPPCFA from the anticipated submission portal eBRAP (<https://ebrap.org>) or Grants.gov.

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

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

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

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

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

FY24 KCRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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.*

- **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter. The three individual letters of recommendation must include one from the mentor and one from the co-mentor(s) (if applicable) or other independent researchers who have had scientific interaction with the PI.

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 (six-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.

The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the mentor(s).

- **Principal Investigator:** The application should describe the PI’s career goals, demonstrating a strong personal commitment to pursuing an independent career as a leader in kidney cancer research. Describe how the proposed research project and mentoring experience will promote the PI’s development toward becoming an independent kidney cancer researcher. The application should discuss the PI’s research plans and career plans after the completion of this award.
- **Mentor(s):** Describe each mentor or co-mentor’s background and experience in kidney cancer research. Explain how the mentor(s) will assist the PI throughout the period of performance in developing toward independence in kidney cancer research. Provide details on the amount and types of interactions between the mentor(s) and the PI. Describe the track record of each mentor for mentoring early-career investigators in kidney cancer research.
- **Research Project:** Describe the proposed research project, including the background, hypothesis/objective, specific aims, experimental design, methods, and analyses. The application must provide a sound scientific rationale for the proposed project and its feasibility as established through a critical review and analysis of published literature and/or logical reasoning. Preliminary data are not required but

may be included to support the scientific rationale and feasibility of the study. Address potential problem areas and present alternative methods and approaches. Include a statistical analysis plan for the proposed research, if applicable. Explain how cell line authentication and/or statistical rigor of preclinical experiments have been incorporated into the study design, if applicable.

- If animal studies are proposed, applicants should 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 [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>.
- **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.
- **Transcripts:** Include a copy of the PI’s transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the “Full Announcement” page in [Grants.gov](https://www.grants.gov)) in place of the transcript.
- **Mentor Qualifications:** Include a description of the qualifications of the mentor. Specifically address the following:
 - Experience in conducting innovative research
 - Experience in kidney cancer to include publications and active funding
 - Record and success in mentoring doctoral, postdoctoral, and/or clinical trainees
- **Co-Mentor Qualifications:** Include a description of the qualifications of the co-mentor(s). Specifically address the following:
 - Experience in conducting innovative research

- Experience in kidney cancer to include publications and active funding
- Record and success in mentoring doctoral, postdoctoral, and/or clinical trainees
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, “Intangible Property.”
 - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). *Do not duplicate the Data and Research Resources Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP’s Policy on Data & Resource Sharing located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP’s expectations for making data and research resources publicly available.

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

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. Clarity and completeness within the space limits are highly important.

– **Research Plan**

- **Background:** Present the ideas and reasoning behind the proposed work.
- **Objective/Hypothesis:** State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design including appropriate controls.

– **Personnel/Researcher Development Plan**

- The PI’s career goals and potential for a career at the forefront of kidney cancer research.
- The strategy for acquiring the necessary skills, competence, and knowledge to successfully complete the proposed research project.
- The mentor’s (and co-mentor’s, if applicable) background and experience in kidney cancer research and proposed contribution to the career development of the PI.

- **Impact**
 - Describe how the proposed project will have an impact on kidney cancer research and/or patient care.
 - How the proposed research project will prepare the PI for a career at the forefront of kidney cancer research.
- **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.*
- 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?
 - If the research is too basic for near-term clinical applicability, describe the interim outcomes.
- Describe the PI’s career goals in kidney cancer research and/or patient care.
 - How does the research plan support the PI in achieving these goals?
 - How does the mentorship and researcher development plan support the PI in achieving these goals?
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Postdoctoral and Clinical Fellowship Award, refer to the “***Suggested SOW Strategy Generic Research***” for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Researcher Development Plan (one-page limit): Upload as “ResearchDev.pdf”.**
 - Clearly articulate an **individualized strategy** that will enable the PI to acquire the necessary skills, competence, and knowledge to successfully complete the proposed research project.
 - Indicate how the **individualized researcher** development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in the field of kidney cancer, and effectively prepare the PI for a career as an independent kidney cancer researcher.
 - Highlight the unique features of the PI’s researcher development plan as it pertains specifically to kidney cancer.
 - Describe how the researcher development plan is supported by the environment and mentorship, including a description of ongoing kidney cancer research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PI’s primary institution (if applicable). If the PI will be utilizing resources at another institution to successfully complete the proposed project, then the PI is strongly encouraged to designate a co-mentor at the collaborating institution. Include information on collaborations with other investigators, seminars, workshops, and other opportunities for professional interaction with leaders in the kidney cancer field. ***Do not reference or include members of the FY24 KCRP Programmatic Panel.***
- **Attachment 7: Impact Statement (one-page limit): Upload as “Impact.pdf”.** The Impact Statement should be written in lay language so that it can be readily understood by readers without a background in science or medicine.
 - Describe the short-term impact: Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research, including any clinically relevant results. Summarize how the anticipated outcome(s)/product(s) address(es) and will help provide a solution to one or more of the FY24 PCRCP Overarching Challenges.
 - Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including the anticipated advantages that the new understanding may contribute to the goal of eliminating death and suffering from kidney cancer and enhancing the well-being of Service Members and their Families, Veterans, and all the American Public who are experiencing the impact of the disease.
 - Describe how the proposed research project and mentoring experience will bring the PI to the forefront of kidney cancer research.

- **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: Eligibility Statement (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 requirements for their doctoral degree, and the date (month/year) the PI began/will begin postdoctoral research in the proposed setting.
 - **Attachment 10: Representations (Extramural Submissions Only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
 - **Attachment 11: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as “IGBudget.pdf”.** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the “Suggested Intragovernmental/Intramural Budget Form”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The

National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
 - **Key Personnel Biographical Sketches (five-page limit each):** Upload as “Biosketch_LastName.pdf”.
 - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.
- (e) Research & Related Budget:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.
- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.
- (f) Project/Performance Site Location(s) Form:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.
- (g) Research & Related Subaward Budget Attachment(s) Form (if applicable, Extramural Submissions Only):** Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.
- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
 - **Intramural DOD Subaward:** Complete a separate “[Suggested Intragovernmental/Intramural Budget Form](#)” for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

Additional Application Components

In addition to the complete application package, FY24 KCRP Postdoctoral and Clinical Fellowship Award applications also require the following components:

Three Confidential Letters of Recommendation (two pages per letter recommended)

The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application. The PI will not be able to view the letters.

- ***The confidential letter of recommendation from each mentor*** should include a description of the mentor’s commitment to the PI’s career development, mentorship in kidney cancer

research, and ability to supervise the PI's research project. Mentor letters should also address the following (two pages per letter recommended):

- The PI's potential for a highly productive career as an independent kidney cancer researcher.
 - Details of the proposed interactions of the mentor with the PI during the PI's research project.
 - The mentoring environment, including ongoing kidney cancer research in the mentor's laboratory and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a kidney cancer researcher.
 - The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application, if funded.
- ***Additional confidential letter(s) of recommendation*** should describe the PI's unique qualifications and accomplishments that highlight their potential for success in pursuing a career in kidney cancer research. At least one of the additional letter(s) should be provided by a former, ***not the current***, mentor. Specifically, each letter should offer the writer's perspective on:
 - The PI's qualifications, characteristics, and achievements.
 - The PI's potential for productivity and desire for establishing a successful and independent career in kidney cancer research.
 - The relevance of the proposed research project to developing the PI's career in kidney cancer research.
 - The suitability of the mentor(s) and the research environment for providing the PI with a solid foundation to support an independent career in kidney cancer research.

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

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including

subaward budget(s) and subaward budget justification(s), may be changed until the end of the [application verification period](#). The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/content/home>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

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

II.D.5. Funding Restrictions

The maximum period of performance is **3** years. *The period of performance is not to exceed 3 years.*

The application’s direct costs budgeted for the entire period of performance should not exceed **\$195,000**. 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 **3** years.

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

- Research costs
- Salary/Stipend (*PI only*)
- Research workshops
- Support for multidisciplinary collaborations
- For one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information of disseminate project results from the KCRP PCFA.

- Travel in support of multi-institutional collaborations.

Must not be requested for:

- Clinical trial costs
- Mentor or other salary
- General office supplies, including computers and software

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:

- **Principal Investigator**
 - How well the PI's achievements (as reflected by academic performance, awards, achievements/honors, and/or previous publications and funding) indicate the potential for a successful career as a kidney cancer researcher.
 - To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a leader in kidney cancer research.
 - To what extent the letters of recommendation from the mentor(s) and others support the PI's potential for a highly productive career as an independent kidney cancer researcher.
 - Whether the PI's proposed level of effort is appropriate for successful completion of the proposed work.
- **Mentor(s)**
 - Whether there is at least one mentor who is an established kidney cancer researcher, as evidenced by a demonstrated record of active funding and recent publications in kidney cancer research.
 - To what extent the mentor's (and co-mentor's, if applicable) own experience in kidney cancer and their ongoing research program and available resources support the ability to supervise the PI's research project.

- To what extent the potential for successful mentoring of the PI in kidney cancer research is indicated in the track record(s) of the mentor(s) in previously mentoring early-career investigators.
- Whether a high level of commitment to the PI's development as an independent kidney cancer researcher is indicated in the mentor letter(s).
- Whether the quality of the application suggests that the mentor(s) provided appropriate guidance in its preparation.
- **Research Strategy and Feasibility**
 - To what extent the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, kidney cancer-relevant preliminary data (if included), and/or logical reasoning.
 - Whether the experimental design and the statistical analysis plan, if applicable, are appropriate for the research proposed.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How well the application acknowledges potential problems and addresses alternative approaches.
 - If applicable, to what degree the intellectual and material property plan is appropriate.
 - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment is appropriate for the proposed research.
- **Researcher Development Plan and Environment**
 - How well the application outlines an individualized researcher development plan that will enable the PI to acquire the necessary skills, competence, and knowledge to successfully complete the proposed research project.
 - How well the individualized researcher development plan will provide the PI with an opportunity to develop a research project, investigate a problem or question in kidney cancer research, and effectively prepare them for a career as an independent kidney cancer researcher.
 - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including professional interaction with established kidney cancer researchers.

- To what extent the research requirements are adequately supported by the availability and accessibility of facilities and resources (including collaborative arrangements as applicable).

- **Impact**

- Assuming the objectives/goals of the proposed research project are realized, to what degree:
 - The anticipated short-term outcome(s)/product(s) of the project will address and provide a solution to one or more of the [FY24 KCRP Focus Areas](#).
 - The proposed research would, in the long term, make a major impact and contribute to the KCRP priorities of reducing death and suffering from kidney cancer.
 - To what degree the proposed research project and mentoring experience will bring the PI to the forefront of kidney cancer research.

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

- **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 priorities of the Defense Health Program and FY24 KCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Alignment with the Overarching Strategic Goals in [Section II.A.1](#)

- Program portfolio composition
- Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.health.mil/about/2tierRevProcess>.

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

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local 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.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.
- The application fails to demonstrate access to the relevant study population or resources.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance <i>(Extramural submissions only)</i>	<input type="checkbox"/>
Summary (Tab 1) and Application Contacts (Tab 2) <i>(Intramural submissions only)</i>	<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"/>
Researcher Development Plan – Attachment 6, upload as “ResearchDev.pdf”	<input type="checkbox"/>
Impact Statement – Attachment 7, upload as “Impact.pdf”	<input type="checkbox"/>
Public Health Service Inclusion Enrollment Report – Attachment 8, upload as “PHS.pdf” if applicable	<input type="checkbox"/>
Eligibility Statement – Attachment 9, upload as “Eligibility.pdf”	<input type="checkbox"/>
Representations <i>(Extramural submissions only)</i> – Attachment 10, upload as “RequiredReps.pdf”	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form <i>(if applicable)</i> – Attachment 11, upload as “IGBudget.pdf”	<input type="checkbox"/>
Research & Related Personal Data	<input type="checkbox"/>
Research & Related Senior/Key Person Profile (Expanded)	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>
Research & Related Budget <i>(Extramural submissions only)</i> Include budget justification	<input type="checkbox"/>
Budget <i>(Intramural submissions only)</i> Include budget justification	<input type="checkbox"/>
Project/Performance Site Location(s) Form	<input type="checkbox"/>
Research & Related Subaward Budget Attachment(s) Form <i>(if applicable)</i>	<input type="checkbox"/>
Additional Application Components	<input type="checkbox"/>
Confidential Letters of Recommendation	<input type="checkbox"/>

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PCFA	Post Doctoral and Clinical Fellowship Award
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