

# **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: W81XWH-20-KCRP-IDA**

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

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 2, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, September 23, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, September 30, 2020
- **Peer Review:** November/December 2020
- **Programmatic Review:** January/February 2021

*This Program Announcement must be read in conjunction with the General Application Instructions, version 501. 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.”*

## TABLE OF CONTENTS

<b>I. OVERVIEW OF THE FUNDING OPPORTUNITY.....</b>	<b>1</b>
<b>II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY.....</b>	<b>3</b>
II.A. Program Description.....	3
II.A.1. KCRP Strategic Plan .....	3
II.A.2. FY20 KCRP Areas of Emphasis (Revised for FY20).....	3
II.A.3. Award History .....	4
II.B. Award Information .....	4
II.C. Eligibility Information.....	8
II.C.1. Eligible Applicants .....	8
II.C.2. Cost Sharing.....	9
II.C.3. Other .....	9
II.D. Application and Submission Information.....	9
II.D.1. Address to Request Application Package .....	10
II.D.2. Content and Form of the Application Submission .....	10
II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM) .....	23
II.D.4. Submission Dates and Times.....	24
II.D.5. Funding Restrictions.....	25
II.D.6. Other Submission Requirements .....	26
II.E. Application Review Information .....	26
II.E.1. Criteria .....	26
II.E.2. Application Review and Selection Process.....	29
II.E.3. Integrity and Performance Information.....	30
II.E.4. Anticipated Announcement and Federal Award Dates.....	30
II.F. Federal Award Administration Information .....	31
II.F.1. Federal Award Notices.....	31
II.F.2. Administrative and National Policy Requirements .....	31
II.F.3. Reporting.....	32
II.G. Federal Awarding Agency Contacts.....	32
II.G.1. CDMRP Help Desk .....	32
II.G.2. Grants.gov Contact Center .....	33
II.H. Other Information.....	33
II.H.1. Program Announcement and General Application Instructions Versions.....	33
II.H.2. Administrative Actions.....	33
II.H.3. Application Submission Checklist .....	36
<b>APPENDIX 1: ACRONYM LIST .....</b>	<b>38</b>

## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

Applications to the Fiscal Year 2020 (FY20) Kidney Cancer Research Program (KCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The KCRP was initiated in 2017 to provide support for research of exceptional scientific merit in the area of kidney cancer. Appropriations for the KCRP from FY17 through FY19 totaled \$45 million (M). The FY20 appropriation is \$40M.

The KCRP’s vision is to eliminate kidney cancer through collaboration and discovery. The KCRP’s mission is to promote rigorous, innovative, and high-impact research in kidney cancer for the benefit of Service members, Veterans, and the American public.

#### II.A.1. KCRP Strategic Plan

The KCRP has prepared a brief synopsis, the KCRP Strategic Plan, which describes KCRP’s background and overview, the research funding environment, and strategic direction for the program. Applicants are strongly encouraged to read and consider the KCRP Strategic Plan before preparing their applications. The KCRP Strategic Plan may be found at <https://cdmrp.army.mil/kcrp/pdfs/KCRP%20Strategic%20Plan.pdf>.

#### II.A.2. FY20 KCRP Areas of Emphasis (Revised for FY20)

Idea Development Award applications are strongly encouraged to address at least one of the FY20 KCRP Areas of Emphasis, as presented in the chart below.

Treatments/Survivorship	Basic/Translational Science	Diagnostic/Prognostics/ Biomarkers	Population-Based Studies
<ul style="list-style-type: none"> <li>• Noninvasive Interventions</li> <li>• Surgical Interventions</li> <li>• Therapeutic Development</li> <li>• Understanding and Managing Toxicity</li> <li>• Survivorship and Patient Experience</li> </ul>	<ul style="list-style-type: none"> <li>• Genetics</li> <li>• Chromatin and Gene Regulation</li> <li>• Metabolism</li> <li>• Microenvironment and Immunology</li> <li>• Environmental Exposures (and/or Deployment-Related Exposures)</li> <li>• New Disease Model Systems</li> <li>• Rare Kidney Cancers</li> <li>• Mechanisms of Response and Resistance</li> </ul>	<ul style="list-style-type: none"> <li>• Prognosis</li> <li>• Biomarker Development</li> <li>• Novel Imaging Technologies</li> <li>• Liquid Biopsy</li> <li>• Microbiome</li> <li>• Disease Disparities</li> </ul>	<ul style="list-style-type: none"> <li>• Screening and Early Detection</li> <li>• Surveillance</li> <li>• Outcome/Population-Based Studies</li> <li>• Environmental Exposures (and/or Deployment-Related Exposures)</li> <li>• Disease Disparities</li> </ul>

### II.A.3. Award History

The KCRP Idea Development Award mechanism was first offered in FY17. Since then, 256 Idea Development Award applications have been received (203 Established Investigators [EIs] and 53 Early Career Investigators [ECIs]), and 34 have been recommended for funding (24 EIs and 10 ECIs).

For FY20, the KCRP Idea Development Award mechanism with distinct funding levels based on specific areas of investigation is being offered for the first time.

### II.B. Award Information

The FY20 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 relevant to active duty Service members, Veterans, other military beneficiaries, and the American public. Personnel on the proposed team should have a strong background in kidney cancer research.

***This funding opportunity is open to applicants with eligible EIs and ECIs named as the Principal Investigator (PI).*** The FY20 KCRP expects to fund one or more scientifically meritorious application(s) with an ECI named as the PI. ECIs will be assessed using different criteria for personnel during the review process (refer to [Section II.E.1.a, Peer Review](#)).

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 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 FY20 KCRP Areas of Emphasis.

**Personnel:** Personnel are considered a crucial element of the FY20 KCRP Idea Development Award. The application should demonstrate the investigators' experience in kidney cancer through the PI's background, the research team, or through collaboration. Collaborations should be documented.

- **An EI** is defined as an independent investigator at or above the level of Assistant Professor (or equivalent) and be 10 years or more from completing a terminal degree. The EI should have kidney cancer-related experience and background as demonstrated by funding and publication records. The EI should plan research collaborations and dedicate a level of effort appropriate for the successful conduct of the proposed work.
- **An ECI** is defined as an independent investigator at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and be less than 10 years from completing their terminal degree (excluding time spent in medical residency or during family medical leave) at the time of the application submission deadline. This should be clearly articulated by the applicant in their biographical sketch. ***Time spent as a postdoctoral fellow is not excluded and must be within the 10-year span from the time of terminal degree.*** Postdoctoral fellows are not eligible for ECI designation. The ECI's training (postdoctoral or clinical) should demonstrate the ECI's ability to accomplish the proposed work. Institutional commitment beyond financial backing such as, but not limited to, independent laboratory space, dedicated research time, and potential collaborations should be demonstrated. The level of effort dedicated to the proposed work by the ECI should be appropriate for the successful conduct of the research project. ***A Career Guide is required and a Career Development Plan is required to be submitted (by ECIs only).***

The ECI must identify an individual whose role in the project is to provide career guidance for the ECI. This individual will be the designated **Career Guide**:

- The Career Guide must hold a position at or above the level of an Associate Professor (or equivalent).
- The Career Guide must have a proven publication, patent, and/or funding record in kidney cancer research.
- The Career Guide must provide a letter of support.

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.

- **Early Detection Studies Option:** Basic or preclinical research that focuses on biomarkers, improved imaging capabilities, and/or new technologies that may foster new paradigms for the early detection of kidney cancer. With justification, applications under the Early Detection Studies Option may request a higher level of funding within the defined period of performance. Such studies may require additional resources due to the participation of human subjects and/or use of human biospecimens.
- **Population Science and Prevention Studies Option:** Preclinical population-based, epidemiology, or public health research that is already supported by substantial preliminary or published data and strongly validates clinical translation in a well-defined context within the kidney cancer field. With compelling justification, applications under the Population Science and Prevention Studies Option may request higher levels of funding within the defined period of performance. Such studies may require additional resources due to the participation of human subjects and/or use of human biospecimens. Use of data and/or biospecimens from active duty Service members and/or Veterans groups is encouraged.

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

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

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 FY20 KCRP priorities.

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

The anticipated direct costs budgeted for the entire period of performance for an FY20 KCRP Idea Development Award will not exceed **\$600,000**.

The anticipated direct costs budgeted for the entire period of performance for an FY20 KCRP Idea Development Award – Early Detection Studies Option will not exceed **\$650,000**.

The anticipated direct costs budgeted for the entire period of performance for an FY20 KCRP Idea Development Award – Population Science and Prevention Studies Option will not exceed **\$2M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

*The CDMRP expects to allot approximately \$18.1M to fund approximately 14 Idea Development Award applications. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.*

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. *Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.* Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

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

**Use of DoD or Department of Veterans Affairs (VA) Resources:** If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to [Section II.D.2.b.ii, Full](#)

[Application Submission Components](#), for detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

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

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.**

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

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

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

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

**USAMRAA makes awards to eligible organizations, not to individuals.**

### **II.C.1.b. Principal Investigator**

**Established Investigators:** Independent investigators at or above the level of Assistant Professor (or equivalent) and 10 years or more from completing a terminal degree are eligible for EI designation.

**Early-Career Investigators:** Independent investigators at the level of Assistant Professor, Instructor, or Assistant Research Professor (or equivalent) and less than 10 years from completing their terminal degree (excluding time spent in medical residency or during family medical leave) at the time of application submission deadline are eligible for ECI designation. ***Postdoctoral fellows are not eligible for ECI designation.***



***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.

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

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

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

## **II.D. Application and Submission Information**

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

### ***Extramural Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at Grants.gov.

### ***Intramural DoD Submission:***

- Pre-application content and forms must be accessed and submitted at [eBRAP.org](http://eBRAP.org).
- Full application packages must be accessed and submitted at [eBRAP.org](http://eBRAP.org)

*Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.*

### **II.D.1. Address to Request Application Package**

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

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

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

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

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

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

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

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

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

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

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

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

***When starting the pre-application, PIs should ensure that they have selected the appropriate application category:***

- Idea Development Award - Established Investigator
- Idea Development Award - Established Investigator - Early Detection Studies Option
- Idea Development Award - Established Investigator - Population Science and Prevention Studies Option
- Idea Development Award - Early-Career Investigator
- Idea Development Award - Early-Career Investigator - Early Detection Studies Option
- Idea Development Award - Early-Career Investigator - Population Science and Prevention Studies Option

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

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

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

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

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

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

[FY20 KCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY20 KCRP Areas of Emphasis or other critical kidney cancer issues 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 sessions.

- **Tab 6 – Submit Pre-Application**

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

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

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

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

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should

be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

**Table 1. Full Application Submission Guidelines**

Extramural Submissions	Intramural DoD Submissions
<b>Application Package Location</b>	
Download application package components for W81XWH-20-KCRP-IDA from Grants.gov ( <a href="https://www.grants.gov">https://www.grants.gov</a> ) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-20-KCRP-IDA from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).
<b>Full Application Package Components</b>	
<b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.	<b>Tab 1 – Summary:</b> Provide a summary of the application information. <b>Tab 2 – Application Contacts:</b> This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Research &amp; Related Personal Data</a></li> <li>• <a href="#">Research &amp; Related Senior/Key Person Profile (Expanded)</a></li> <li>• <a href="#">Research &amp; Related Budget</a></li> <li>• <a href="#">Project/Performance Site Location(s) Form</a></li> <li>• <a href="#">Research &amp; Related Subaward Budget Attachment(s) Form</a> (if applicable)</li> </ul>	<b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <a href="#">Attachments</a></li> <li>• <a href="#">Key Personnel</a></li> <li>• <a href="#">Budget</a></li> <li>• <a href="#">Performance Sites</a></li> </ul> <b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
<b>Application Package Submission</b>	
Create a Grants.gov Workspace.	Submit package components to eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).

Extramural Submissions	Intramural DoD Submissions
<p>Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b> An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>	<p><b>Tab 5 – Submit/Request Approval Full Application:</b> After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official by email. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>
<b><u>Application Verification Period</u></b>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>
<b>Further Information</b>	
<p><b>Tracking a Grants.gov Workspace Package.</b> After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

Extramural Submissions	Intramural DoD Submissions
<p>number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

**Attachments:**

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

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

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

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research. Describe previous experience most pertinent to the application. Preliminary data in kidney cancer research is preferred but not required. State the FY20 KCRP Area(s) of Emphasis to be addressed; if an Area of Emphasis will not be addressed, explain

how the study will investigate an important gap in kidney cancer research or patient care.

- **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:** Describe the experimental design, methods, and analyses in sufficient detail for evaluation including availability of resources (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 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.*
- **Personnel:** Explain the degree to which the proposed research demonstrates a critical understanding and in-depth knowledge of kidney cancer.
  - **For EIs only:** Describe how the kidney cancer-related experience and background of the research team, and their levels of effort, are appropriate to accomplishing the proposed work.
  - **For ECIs only:** Describe how the PI’s previous training (postdoctoral or clinical) and level of effort by the PI, Career Guide, and other key personnel are appropriate to accomplishing the proposed work. Explain the unique features of the research environment, including collaborations, and how they are integrated into the Career Development Plan. Address the status of the Career Guide as an independent, established researcher in kidney cancer as demonstrated by a record of publications, patents, and/or funding history. Describe the extent to which the Career Guide’s track record in guiding ECIs indicates the potential for advancement of the PI’s independent research career in 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. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.



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

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.
- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), “Intangible Property.”
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research

community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.
- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Programmatic reviewers typically do not have access to the full application and 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.

**The technical abstract should address the following elements:**

- Background: Present the ideas and reasoning behind the proposed research.
- Areas of Emphasis: State the FY20 KCRP Area(s) of Emphasis to be addressed; if an Area of Emphasis will not be addressed, state an important gap in kidney cancer research or patient care on which the study will focus.
- 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 FY20 KCRP Areas of Emphasis, or otherwise an important gap in kidney cancer research or patient care. Summarize how the proposed project is relevant to and will have an impact on those affected by kidney cancer and/or the understanding of kidney cancer.

- 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. Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid use of acronyms and abbreviations, if possible.

- 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 FY20 KCRP Area(s) of Emphasis to be addressed; if an Area of Emphasis is not to be addressed, state an important gap in kidney cancer research or patient care on which the study will focus.
- 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”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Idea Development Award mechanism, use the SOW format example titled, “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/subaward site.

- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.
- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf”.**
  - Explain why the proposed research project is important to understanding the causes and progression of kidney cancer and/or to realizing improvements in patient care and/or quality of life.
  - 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.
  - If the proposed research project is high-risk, explain the potential gain from accomplishing the work and finding the outcomes.

- **Attachment 8: Submissions Statement (one-page limit): Upload as “Submissions.pdf”.** (*Attachment 8 is only applicable and required for applications in which the PI is named in multiple FY20 KCRP Idea Development Award applications. Attachment 8 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 9: Career Development Plan (one-page limit), if applicable (required for ECIs only): Upload as “CareerDev.pdf”.**
  - Clearly describe and outline the individualized Career Development Plan and highlight the unique features of the Career Development Plan as it pertains specifically to kidney cancer research, including potential collaborations, and their appropriateness in advancing the independent career of the PI.
  - Indicate specifically how the individualized Career Development Plan will provide the PI with an opportunity to advance their independent career in kidney cancer research.
  - Describe how the Career Development Plan is supported by the research environment and career guidance, including a description of ongoing cancer research at the institution relevant to kidney cancer research. Include information on collaborations with other investigators.
- **Attachment 10: Letter of Eligibility Statement (one-page limit), if applicable (required for ECIs only): Upload as “Eligibility.pdf”.** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official verifying that the eligibility requirements will be met. For more eligibility details, refer to [Section II.B, Award Information](#), and [Section II.C, Eligibility Information](#).
- **Attachment 11: Letter from Career Guide (two-page limit), if applicable (required for ECIs only): Upload as “CareerGuideLetter.pdf”.** Provide a signed letter from the Career Guide indicating recommendation, support, and planned interactions with the PI for the proposed work. The letter from the Career Guide should detail individualized interaction between the Career Guide and the PI for further career development. Include information on the Career Guide’s record of preparing ECIs for careers in kidney cancer research.
- **Attachment 12: Representations, if applicable (extramural submissions only): Upload as “RequiredReps.pdf”.** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/>)

[public/Program.htm](https://eBRAP/public/Program.htm)). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 13: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DoD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

- PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://eBRAP/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”.
  - Include biographical sketch of Career Guide (required for ECIs only)

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - Include Career Guide’s previous/current/pending support (required for ECIs only)

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

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

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

- **Extramural Applications Only**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the “Suggested Collaborating DoD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 13](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

#### **II.D.4. Submission Dates and Times**

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

#### **Applicant Verification of Full Application Submission in eBRAP**

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

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

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



Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

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

#### **II.D.5. Funding Restrictions**

##### **Idea Development Award**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$600,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$600,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **Idea Development Award with Early Detection Studies Option**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$650,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$650,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **Idea Development Award with Population Science and Prevention Studies Option**

- The maximum period of performance is **4** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$2M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$2M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **For All Funding Options**

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 be less than the maximum period of performance.

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

- Travel in support of multidisciplinary collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year to present project information or disseminate project results and/or attend workshops.

Must not be requested for:

- Clinical trial costs

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

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

## **II.D.6. Other Submission Requirements**

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

## **II.E. Application Review Information**

### **II.E.1. Criteria**

#### **II.E.1.a. Peer Review**

To determine technical merit, all applications will be evaluated according to the following **scored criteria**, which are 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.
- **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 FY20 KCRP Areas of Emphasis; or if it does not address one of the FY20 KCRP Areas of Emphasis, whether it addresses an important gap in kidney cancer research or patient care.
  - 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**

- **For EIs only:** Whether the PI meets the eligibility requirements as an EI.
  - To what degree the kidney cancer-related experience and background represented on the research team are appropriate to accomplishing the proposed work.
  - To what extent the levels of effort are appropriate to accomplishing the proposed work.
- **For ECIs only:** Whether the PI meets the eligibility requirements as an ECI.
  - Whether the PI's previous training (postdoctoral or clinical) supports the abilities of the PI to accomplish the proposed work.
  - Whether the institution, through its Letter(s) of Organizational Support, has demonstrated commitment (i.e., independent laboratory space, equipment, and other resources).
  - To what extent the levels of effort are appropriate for successful conduct of the proposed work.
  - To what degree the proposed Career Development Plan is appropriate and will prepare the PI for a successful, independent career at the forefront of kidney cancer research.
  - Appropriateness of the levels of effort by the PI, Career Guide, and other key personnel to ensuring the success of this research effort.
  - To what extent unique features of the research environment are integrated into the Career Development Plan, including potential collaborations, and how appropriate the features are to advancing the independent career of the PI.
  - Whether the Career Guide is an independent, established researcher in kidney cancer research as demonstrated by a record of publications, patents, and/or funding history.
  - To what degree the Career Guide demonstrates an individualized plan for interaction between the Career Guide and the PI for further career development.
  - To what degree the Career Guide's track record in guiding ECIs indicates the potential for successful guidance and advancement of the PI's independent research career in kidney cancer.

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

- **Environment**

- To what degree the scientific environment is appropriate for the proposed research.

- To what degree the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- To what degree the quality and extent of institutional support are appropriate.
- If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
  - Whether the **direct** maximum costs exceed the allowable direct maximum costs as published in the Program Announcement.
  - Whether the budget is appropriate for the proposed research.
  - Whether there is potential overlap with existing or pending awards of the PI, as demonstrated by the PI's Biographical Sketch and Previous/Current/Pending Support document.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY20 KCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Programmatic relevance to the FY20 KCRP Area(s) of Emphasis or a critical gap in kidney cancer research or patient care
  - 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, on behalf of the DHA and the OASD(HA). *The highest-scoring*

*applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#). Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the KCRP will be provided to the PI and posted on the CDMRP website.*

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

### **II.E.3. Integrity and Performance Information**

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

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

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

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

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

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

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

Awards supported with FY20 funds are anticipated to be made no later than September 30, 2021. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

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

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

**Federal Government Organizations:** Funding made to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

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

Unless otherwise restricted, changes in PI or organization will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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

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

#### **II.F.1.b. Pre-Award Meeting**

### **II.F.2. Administrative and National Policy Requirements**

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

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

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

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

### **II.F.3. Reporting**

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

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

The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. CDMRP Help Desk**

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP



should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

## **II.G.2. Grants.gov Contact Center**

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

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

Email: [support@grants.gov](mailto:support@grants.gov)

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

## **II.H. Other Information**

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

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

### **II.H.2. Administrative Actions**

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

#### **II.H.2.a. Rejection**

The following will result in administrative rejection of the application:

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

### **II.H.2.b. Modification**

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

### **II.H.2.c. Withdrawal**

The following may result in administrative withdrawal of the application:

- An FY20 KCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY20 KCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/kcrp/panels/panels20>.*
- The application fails to conform to this Program Announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- A clinical trial is proposed.
- The PI does not meet the eligibility criteria.

#### **II.H.2.d. Withhold**

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

### II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 Research & Related Application for Federal Assistance ( <b>extramural submissions only</b> )	Complete form as instructed	
Summary (Tab 1) and Application Contacts (Tab 2) ( <b>intramural submissions only</b> )	Complete tabs as instructed	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"	
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf"	
	Submissions Statement: Upload as Attachment 8 with file name "Submissions.pdf" if applicable	
	Career Development Plan: Upload as Attachment 9 with file name "CareerDev.pdf" if applicable	
	Letter of Eligibility Statement: Upload as Attachment 10 with file name "Eligibility.pdf" if applicable	
	Letter from Designated Career Guide: Upload as Attachment 11 with file name "CareerGuideLetter.pdf" if applicable	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable	
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable	

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

## APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
ACURO	Animal Care and Use Review Office
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
COI	Conflict of Interest
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ECI	Early-Career Investigator
EI	Established Investigator
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDA	Idea Development Award
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans Affairs