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

Clinical Research Nurse Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-21-KCRP-CRNDA

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

SUBMISSION AND REVIEW DATES AND TIMES

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

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

TABLE OF CONTENTS

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

II.A.1. KCRP Overarching Strategic Goals

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

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

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

Clinical Research Nurse Development Award applications are encouraged, but not required, to address at least one of the FY21 KCRP Focus Areas, as presented below. **If applicable, selection of the Focus Area(s) is the responsibility of the applicant.**

- Conduct basic biology research to better understand etiology and cancer progression, metastatic disease, refractory disease and therapeutic resistance, genetic and environmental risk factors and the prevention of kidney cancer.

- Identify and develop new strategies for screening, early-stage detection, accurate diagnosis and prognosis prediction of kidney cancers, with examples including biomarkers and imaging.

- Define the biology of rare kidney cancers and develop treatments to improve outcomes and reduce death.

- Develop novel therapeutic strategies for the treatment of kidney cancer, such as novel drug targets, therapeutic modalities and agents, treatment combinations and drug delivery systems.

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

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

- Clear Cell Renal Cell Carcinoma (ccRCC)
- Papillary RCC
- Chromophobe RCC
- Collecting duct carcinoma
- Translocation RCC
- Renal medullary carcinoma (RMC)
- Transitional cell carcinoma (TCC)
- Wilms tumor (nephroblastoma)
- Renal sarcoma
- Angiomyolipoma
- Oncocytoma
- Unclassified/Not applicable

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

II.A.3. Award History

The KCRP Clinical Research Nurse Development Award (CRNDA) mechanism was offered for the first time in FY20. Two applications were received and one award was made.

II.B. Award Information

The inclusion of clinical trial research nurses on a multi-disciplinary clinical research team is thought to be a valuable asset in executing the day-to-day management of a clinical trial. Clinical research nurses (CRNs) perform an essential role to ensure that the integrity and quality of clinical trials are maintained while also safeguarding the welfare of clinical research and/or trial participants. CRNs are involved in all aspects of the clinical trial continuum from the initial development of a trial protocol through post study patient care, trial closeout, and dissemination of research findings (please refer to Appendix 2 and Appendix 3 for references that may be

useful to CRNs). During the past 20 years there has been an increase in the number of CRNs as well as a rise in training and certification programs for this specialty, although the overall number of nurses with clinical trial research expertise remains low (Poston, 2010). Some factors that have impeded a more significant increase in CRNs are lack of educational resources, limited financial support, and ability to access hands-on training by experienced CRNs and in research settings. The intent of the Clinical Research Nurse Development Award is to support research that allows the preparation of nurses for the kidney cancer CRN specialization through a mentored research training approach.

Clinical research requires a team of collaborating members and is most productive in settings where all team members are experienced and striving to work at the top of their capacity to advance novel therapeutics or the medical treatment field. Developing a workforce of highly skilled and knowledgeable CRNs requires a comprehensive, interdisciplinary clinical research experience to foster active roles in clinical trial management, protocol adherence, industry/institution and regulatory collaborations, and patient education. The FY21 KCRP Clinical Research Nurse Development Award funds research that is supported by mentoring partnerships between a clinician (i.e., physician, physician scientist, or equivalent) and a CRN coordinator (or equivalent) to pilot a CRN fellowship program that will enable the advancement of credentialed nurses to pursue dynamic careers in collaborative kidney cancer clinical research.

The Clinical Research Nurse Development Award requires more than one Principal Investigator (PI). One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Initiating and Partnering PIs, refer to Section II.D.2, Content and Form of the Application Submission.

Key components of this award mechanism are as follows:

Research Approach: The proposed research project must have high potential to lead to or make breakthroughs in kidney cancer. The proposal must pursue a kidney cancer project and explicitly state the involvement of CRN trainees in conducting and assessing the clinical trial research project. 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. The inclusion of preliminary data relevant to kidney cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from both the Initiating and Partnering PIs; additionally, required resources should be identified and supported through documentation.

Projects supported by this award should be relevant and accessible to the CRN, and may vary from typical clinical trials or translational scientific work. Below is a list of the types of projects that this award is intended to support (not all-inclusive):

- Projects that develop education programs for CRN onboarding
- Projects that develop professional development model for CRNs
- Projects that elevate the CRN role within nursing
- Projects that develop best practice models for CRN support of clinical trials

Impact: Research supported by the Clinical Research Nurse Development Award will have the potential for a major impact and accelerate progress toward ending kidney cancer and/or improving patient care for those participating in kidney cancer clinical trials. The impact may be short term or long term but must move beyond an incremental advance. Applications are expected to identify the kidney cancer patients or at-risk individuals who would ultimately benefit from the proposed research.

Principal Investigators (PIs): Each CRNDA application must include one pair of PIs, a clinician and a CRN coordinator (or equivalent), in an equal partnership. The two PIs are the **mentors** of the proposed research nurse development program. The clinician will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The CRN coordinator (or equivalent) will be identified as the Partnering PI. The Initiating PI (clinician) must be the PI, co-PI, or lead of active clinical trials and/or research. The Partnering PI (CRN coordinator or equivalent) must have at least 2 years of cancer or oncology clinical trial research nurse experience. At least one of the PIs in this partnership must demonstrate clinical research experience in kidney cancer. Both PIs should be involved in writing the project narrative, the program's development plan for future research nurse trainees, and other application components. **The PIs do not need to be from the same institution, although an established collaboration must be clearly detailed, and at least one of the PIs must be at the same institution of (prospective) CRN trainees.** ***The proposed research project and career development plan must focus on kidney cancer.*** Applications must emphasize both PIs' potential for success in developing two or more kidney cancer clinical trial research nurses based on their prior track record as mentors, prior experience in developing research training programs, and/or prior experience in kidney cancer clinical research.

PIs/Mentors: The mentors (clinician and CRN coordinator) must possess the appropriate expertise and experience in kidney cancer clinical research, clinical trial research, and/or patient care, to include recent publications, active peer-reviewed kidney cancer funding, and clear demonstration of a commitment to guiding the trainees' development into kidney cancer clinical trial research nurses. The mentors must provide a plan that ensures trainees will have access to clinical trial patients in order to gain hands-on research experience and training (e.g., evidence of an active clinical trial). The application must show how the combined experiences of the mentors will support the award's intent of preparing nurses for kidney cancer research and CRN specialization. Mentorship by an investigator without an established record of mentoring clinical trial nurses may be offset by the overall strength of the career development plan. The mentors should showcase how they intend to dedicate time to this significant effort to directly train and advance trainees to become clinical trial research nurses.

Training Environment: The institution designated as the site of the proposed research and training will be evaluated to determine the presence of strong programs in interdisciplinary kidney cancer research. Successful applicants must have mechanisms in place to ensure that the clinical trial research nurse trainees will have exposure to kidney cancer scientists and clinicians, other trainees, and research teams on an ongoing basis (e.g., through journal clubs and seminars). Applications must demonstrate the training institution has a substantial history of conducting clinical trials and research in kidney cancer. Additionally, applications must demonstrate that there are active and open kidney cancer clinical trials and research at the institution and/or that new kidney cancer clinical trials will be opened and that kidney cancer patients are being recruited at the institution during the proposed period of performance for the training program. Institutions must also demonstrate commitment to retain the trainees or provide evidence of plans to integrate trainees into collaborating institutions following the period of training. **This award is intended to support kidney cancer research and the career development of kidney cancer clinical trial research nurses.**

Career Development Plan: Applications must provide details on the ***kidney cancer research-focused career development plan***, and describe how it will facilitate the trainee's career development as a kidney cancer clinical trial research nurse, enabling the trainee to conduct impactful research. The suitability of the career development plan for attaining the goals of this award mechanism will be a critical component of the evaluation. Applications should provide details on the expected qualities of the planned trainees, evidence of qualified candidates, the selection criteria and process for trainees, and training and research curriculum planned over the period of performance. The research and training curriculum should include a combination of hands-on approaches with both mentors (e.g., shadowing the mentors, shadowing clinicians and patients, attending laboratory meetings, learning laboratory research techniques, interacting with patients under supervision) and trainee self-learning curricula (e.g., attending and participating in conferences, seminars, journal clubs, department-wide didactic meetings). If trainees have been identified, detailed biographical sketches should be included. Career development planning should include the duration of mentored research effort, planned interactions with the PIs and possibly other research and clinical staff, opportunities to gain tangible certifications or degrees (such as the Society of Clinical Research Associates' international certification program, Certified Clinical Research Professionals), opportunities to gain independence in clinical trial research performance and/or to exercise skills in program leadership, team development, or project design. Consideration of the development of communications, networking, finance, regulatory, data management, or other business skills will also be evaluated. A multidisciplinary research approach to kidney cancer is highly encouraged but not required; however, if there are multidisciplinary aspects, they should be clearly outlined in the application.

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

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the 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.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY21 KCRP priorities.

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

The anticipated direct costs budgeted for the entire period of performance for an FY21 KCRP Clinical Research Nurse Development Award will not exceed **$300,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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

The CDMRP expects to allot approximately $0.96M to fund approximately two Clinical Research Nurse 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 FY21 funding opportunity will be funded with FY21 funds, which will expire for use on September 30, 2027.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of

submission is ***not*** required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trial costs will not be supported by this award, but correlative studies to clinical trials may be supported. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

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

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

laboratory or military treatment facility or in a DOD activity embedded within a civilian medical center.

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

As of the application submission deadline:

- The Initiating PI is the clinician PI. The clinician PI must be an independent investigator at or above the level of Assistant Professor (or equivalent) with an M.D. and/or M.D./Ph.D. degree (or equivalent). The clinician PI must have an affiliation with the clinical setting, institution, or collaborating institution involved in the active clinical trial in which the proposed research and training is to be performed. The clinician PI must be the PI, co-PI, or lead of active clinical trial(s) and/or research.

- The Partnering PI is the CRN coordinator. The Partnering PI must be a licensed Registered Nurse with a Bachelor's, Master's or Doctoral degree in nursing. The Partnering PI must also have at least 2 years oncology or cancer clinical trial research nurse experience as well as prior experience mentoring nurses to become clinical trial research nurses. The PI must be in the clinical setting in which the proposed research and training is to be performed by the start of the grant award period.

- At least one of the PIs in this partnership must demonstrate clinical research experience in kidney cancer.

Each investigator may be named on only one KCRP Clinical Research Nurse Development Award application as a PI.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

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

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

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

II.D. Application and Submission Information

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

Extramural Submission:

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

Intramural DOD Submission:

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

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

II.D.1. Address to Request Application Package

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

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

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

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

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

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

The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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

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

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

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

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

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

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

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

- **Tab 1 – Application Information**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at

https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

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

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

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

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

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

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

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

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

- **Tab 6 – Submit Pre-Application**

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

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

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

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

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

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

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

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DOD Submissions
Application Package Location	
Download application package components for W81XWH-21-KCRP-CRNDA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-21-KCRP-CRNDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General	**Tab 1 – Summary:** Provide a summary of the application information.

Extramural Submissions	Intramural DOD Submissions
Application Instructions, Section III.A.1, for detailed information.	**Tab 2 – Application Contacts:** 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: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form (if applicable)	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites **Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. ***Note:*** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to*** the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.***

Extramural Submissions	Intramural DOD Submissions
Application Verification Period	
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 ***with the exception of the Project Narrative and Research & Related Budget Form***.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PIs 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 ***with the exception of the Project Narrative and Research & Related Budget Form***. 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.
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

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

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

- **Extramural Applications Only**

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

- **Extramural and Intramural Applications**

  Attachments:

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

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

- **Attachment 1: Project Narrative (10-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. ***The Project Narrative must be written by both the clinician PI and the CRN coordinator (or equivalent) PI in equal partnership.***

  - **Principal Investigators/Mentors:** The application should describe the Initiating and Partnering PIs' strong commitment to being leaders in kidney cancer clinical trials, research, and/or patient care. Describe both PIs' background and experience in kidney cancer clinical research and oncology/cancer clinical trials. Describe both PIs' ongoing research program(s) and availability of resources to support supervision of the proposed trainees' research project. Application must emphasize both PIs' potential for success in developing two or more kidney cancer clinical trial research nurses. Describe the track record of the PIs for mentoring kidney cancer clinical researchers and oncology/cancer clinical trial research nurses. Explain each PI's anticipated level of effort, how each PI will assist the trainees throughout the period of performance in developing toward independence as kidney cancer clinical trial research nurses and researchers. Provide details of the established collaboration and/or types of interactions between the Initiating and Partnering PIs and on the amount and type of interactions between each PI and the trainees. Beyond the above-mentioned detailed plans about the interactions, please describe how trainees will be supported in applying to a CRN certification program and the role of the Initiating and Partnering PIs/mentors in these processes.

  - **Research Project:** Summarize the research plans for CRN trainees, including opportunities for a stimulating, problem-solving research experience. State the project's hypothesis, objectives, rationale, and specific aims. Describe the scientific rationale, experimental design, and methods to test the hypothesis and the specific aims of the project. Explain how the proposed study will be integrated with the CRN responsibilities, e.g., quality assurance and safety, essential protection of human subjects' information, basic clinical trial management, and data analysis. The research project must involve a clinical trial; however, clinical trial costs may not be supported by this award. Correlative studies to clinical trials are allowed. The application must provide the scientific rationale for the proposed project and its feasibility as established through a review and analysis of published literature, kidney

cancer-relevant preliminary data (if included), and/or logical reasoning. Preliminary data are not required, but may be included to support the scientific rationale and feasibility of the study. Acknowledge and address potential problem areas and present alternative methods and approaches. Include a statistical analysis plan for the proposed research, if applicable.

- **Research Environment:** Describe the strength of the interdisciplinary kidney cancer research program at the applicants' indicated institution(s). Include evidence of substantial history of conducting clinical trials and research in kidney cancer at the institution(s). Describe the active and open kidney cancer clinical trials ongoing at the institution(s). Describe any new clinical trials that are anticipated to be opened for recruitment of kidney cancer patients at the institution during the proposed period of performance. Describe the scientific environment, career development activities, and professional interactions with established kidney cancer clinical researchers of the primary institution (and collaborating institution(s), if applicable) that the trainees will have access to and where training will occur.

- **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.

  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

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

- **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D

confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

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

  Programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  Describe the proposed research project including the following elements:

  - **Research Plan**
    - Background: Present the ideas and reasoning behind the proposed work.
    - Objective/Hypothesis: State the hypothesis to be tested or the objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
    - Specific Aims: State the specific aims of the study.
    - Study Design: Briefly describe the study design including appropriate controls.
  - **Career Development Plan**
    - The strategy for the trainees to acquire the necessary skills, competence, and expertise to successfully complete the proposed research project.
    - The PIs' background and experience in kidney cancer clinical research, oncology clinical trial research nursing, mentoring, and proposed contribution to the career development of the trainees.
    - How the proposed research project will prepare trainees for a clinical trial research nurse career at the forefront of kidney cancer clinical research and patient care.
    - The trainees' potential for a career at the forefront of kidney cancer clinical research and patient care.
  - **Impact**
    - How the proposed project will have an impact on kidney cancer clinical research.
    - How the proposed project will have an impact on the relationship between clinical trial research nurses at the forefront of kidney cancer research and patient care.

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

  The lay abstract should be written using the outline below. ***Do not duplicate the technical abstract***. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine***.

  - Describe the ultimate applicability of the research.

    - What types of patients will it help and how will it help them?

    - What are the potential clinical applications, benefits, and risks?

    - What is the projected time it may take to achieve a patient-related outcome?

    - How will the project, if successful, impact the relationship between clinical trial research nurses at the forefront of kidney cancer research and patient care?

  - Describe the PIs' career goals for clinical trial research nurse trainees in kidney cancer research and/or patient care.

    - How does the research plan support the trainees' development into independent clinical trial research nurses?

    - How does the mentorship and career development plan support the trainees in achieving these goals?

    - How will the CRN development program, if successful, impact the relationship between clinical trial research nurses at the forefront of kidney cancer research and patient care?

- **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). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the FY21 KCRP Clinical Research Nurse Development Award mechanism, refer to the "***Suggested SOW Strategy Clinical Research***" document for guidance on preparing

the SOW and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

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

- Include the name(s) of the key personnel and contact information for each study site/ subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
- Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
- 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: Career Development Plan (one-page limit): Upload as "CareerDev.pdf".**
  - Applications should provide details on the expected qualities of the planned trainees, evidence of qualified candidates, the selection criteria and process for trainees, and training and research curriculum planned over the period of performance.
  - Clearly articulate the strategy that will enable the CRN trainees to acquire the necessary skills, competence, and experience to successfully complete the proposed clinical research project.
  - Indicate how the career development plan will provide the trainee with an opportunity to develop a clinical research project, investigate a problem or question in the field of kidney cancer clinical research and/or patient care, and effectively prepare the trainees for a career as a kidney cancer CRN.
  - Highlight the unique features of the PIs' experiences that will enhance the career development plan as it pertains specifically to kidney cancer clinical research and/or oncologic/cancer clinical trial research patient care.

- Describe how the career development plan is supported by the environment and mentorship, including a description of the primary institution's history of conducting clinical trials in kidney cancer, active and/or pending kidney cancer clinical trials, and ongoing kidney cancer clinical research at the institution. Include a description of the environment of any collaborating institutions that will augment the lack of specific resources at the PIs' primary institution(s) (if applicable). Include information on collaborations with other investigators, seminars, workshops, availability and accessibility of facilities and resources, and other opportunities for professional interaction with leaders in the kidney cancer field. ***Do not reference or include members of the FY21 KCRP Programmatic Panel.***

- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf".** State explicitly how the research project, if successful, will have an impact, in terms of short- or long-term outcomes, on the field of kidney cancer research and/or improved patient care. Explain how the proposed CRN mentored training effort advances the KCRP overarching strategic goal "Grow the field and increase collaboration in the area of kidney cancer" (see *KCRP Strategic Plan,* https://cdmrp.army.mil/kcrp/default). Describe in detail how the CRN development program, if successful, will have a lasting impact on the relationship between clinical trial research nurses at the forefront of kidney cancer research and patient care. ***The Impact Statement should be written in plain language for lay persons.***

- **Attachment 8: PI/Mentor Qualifications Statement (four-page limit): Upload as "Qualifications.pdf".** Include a description of the qualifications of the mentors. Specifically address the following:

  - Experience in conducting innovative research

  - Experience in kidney cancer clinical research to include publications and active funding

  - Experience in oncology/cancer clinical trial research nursing

  - Record of kidney cancer or other cancer research outcomes of the Initiating PI and Partnering PI based as outlined below:

    - Past and current kidney cancer or other cancer research support from both federal and non-federal sources (as applicable) from the past 5 years

    - Any honoraria, awards, or other distinctions received for work in kidney cancer or other cancer research from the past 5 years

    - Any patents or other kidney cancer or other cancer research accomplishments from the past 5 years

  - Record of each PI's role in the active clinical trial that is intended to be the setting of the proposed training program

- Record of any experience and success in mentoring doctoral, postdoctoral, clinical trainees, and/or CRNs

- **Attachment 9: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 10: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using "Suggested Collaborating DOD Military Facility Budget Format", available for download on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

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

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

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

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

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

- For extramural submissions, refer to the General Application Instructions, Section III.A.4 for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

  - Include trainees' biographical sketch (if already identified).

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

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.

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

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 10. (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.

Application Components for the Partnering (CRN Coordinator) PI

The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

The Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

  - **Attachment 9: Representations (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

  - **Attachment 10: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

- 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 trainees' biographical sketch (if already identified).

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

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

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  - **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.)

  - **Intramural DOD Collaborator(s):** Complete a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP "Funding Opportunities & Forms" web page [https://ebrap.org/eBRAP/public/Program.htm]), and upload to Grants.gov attachment form as Attachment 10 (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

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

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through April 2022, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

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

Applicant Verification of Full Application Submission in eBRAP

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

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

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

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

II.D.5. Funding Restrictions

The maximum period of performance is **2** years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **$300,000**. 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 **$300,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Partnering PI: The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$300,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **$300,000** or use an indirect cost rate exceeding each organization's negotiated rate.

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

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

- CRN Partnering PI and trainees' salaries
- Workshops and seminars

- Research nurse training materials (e.g., software, online programs, technological equipment)
- Support for multidisciplinary collaborations, including travel
- Costs for each trainee to travel to one scientific/technical meeting per year to present project information or disseminate project results and/or attend workshops as designated in the Career Development Plan of the KCRP Clinical Research Nurse Development Award

Must not be requested for:

- Clinical trial costs
- Initiating PI's salary

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:

- **Principal Investigators**
    - How well the PIs' achievements and experience (as reflected by academic performance, awards, honors, and/or previous publications and funding) indicate the potential for successfully mentoring kidney cancer clinical trial research nurses.
    - Whether the PIs' proposed level of effort is appropriate for successful completion of the proposed work.

- Whether there is at least one PI/mentor who is an established kidney cancer clinical researcher, as evidenced by a demonstrated record of active funding and recent publications in kidney cancer clinical research.

- To what extent the PIs'/mentors' experience in kidney cancer and their ongoing research program and available resources support the ability to supervise the proposed trainees' research project.

- Application must emphasize both PIs' potential for success in developing two or more kidney cancer clinical trial research nurses.

- To what extent the track record(s) of the PI(s)/mentor(s) in previously mentoring trainees indicate the potential for successful mentoring of award trainees to become independent kidney cancer clinical trial research nurses.

- **Research Strategy and Feasibility**

  - To what extent the scientific rationale supports the project and its feasibility as demonstrated by a review and analysis of published literature, kidney cancer-relevant preliminary data (if included), and/or logical reasoning.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.

  - How well the application acknowledges potential problems and addresses alternative approaches.

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

- **Career Development Plan and Environment**

  - How well the application outlines a career development plan that will enable the trainees to acquire the necessary skills, competence, and experience to successfully complete the proposed research project.

  - How well the proposed research project and the career development plan will provide the trainees with an opportunity to develop a clinical research project, investigate a problem or question in kidney cancer clinical research and/or patient care, and effectively prepare them for a career as a kidney cancer CRN.

  - To what extent the scientific environment at the primary institution (and collaborating institution(s), if applicable) is appropriate for the proposed research and career development activities, including professional interaction with established kidney cancer clinical researchers.

  - To what extent the primary institution's history of conducting clinical trials in kidney cancer, and active and/or pending kidney cancer clinical trials, support an appropriate environment for the trainees' clinical and research training.

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

- **Impact**
  - To what degree the research project, if successful, will have an impact, in terms of short- or long-term outcomes, in the field of kidney cancer research and/or improved patient care.
  - To what extent the CRN development program, if successful, will have a lasting impact on the relationship between clinical trial research nurses at the forefront of kidney cancer research and patient care.

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

- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the FY21 KCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Alignment with the Overarching Strategic Goals
  - Program portfolio composition
  - Relative impact

II.E.2. Application Review and Selection Process

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

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

II.E.3. Integrity and Performance Information

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

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

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

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

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

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

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

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

II.F.2. Administrative and National Policy Requirements

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

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

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

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

II.F.3. Reporting

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

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

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

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

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

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

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

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

Email: support@grants.gov

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

II.H. Other Information

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

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

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- 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 pre-application or application:

- An FY21 KCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY21 KCRP Programmatic Panel members can be found at https://cdmrp.army.mil/kcrp/panels/panels21.***
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY21, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The Initiating PI or Partnering PI does not meet the eligibility criteria.
- A clinical trial is proposed.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI Completed
SF424 Research & Related Application for federal Assistance **(extramural submissions only)**	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)**	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Career Development Plan: Upload as Attachment 6 with file name "CareerDev.pdf"		
	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf"		
	PI/Mentor Qualifications Statement: Upload as Attachment 8 with file name "Qualifications.pdf"		
	Representations (extramural submissions only): Upload as Attachment 9 with file name "RequiredReps.pdf" if applicable		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 10 with file name "MFBudget.pdf" if applicable		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
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 **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Complete the Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	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
CRN	Clinical Research Nurse
CRNDA	Clinical Research Nurse Development Award
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
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	Department of Veterans

APPENDIX 2: PUBLICATION REFERENCES

Faulkner-Gurstein R, Jones HC, McKevitt C. 2019. Like a nurse but not a nurse: Clinical research practitioners and the evolution of the clinical research delivery workforce in the NHS. *Health Res Policy Syst* 17(1):59.

Calvin-Naylor NA, Jones CT, Wartak MM, et al. 2017. Education and training of clinical and translational study investigators and research coordinators: A competency-based approach. Version 2. *J Clin Transl Sci* 1(1):16-25.

Bevans M, Hastings C, Wehrlen L, et al. 2011. Defining clinical research nursing practice: Results of a role delineation study. *Clin Transl Sci* 4(6):421-427.

Poston RD and Buescher CR. 2010. The essential role of the clinical research nurse (CRN). *Urol Nurs* 30(1):55-63, 77.

APPENDIX 3: PROFESSIONAL WEBSITES

American Society of Clinical Oncology
https://www.asco.org

Association of Clinical Research Professionals
https://acrpnet.org/

Eastern Nursing Research Society
http://communities.enrs-go.org/home

International Association of Clinical Research Nurses
https://iacrn.org/

Kidney Cancer Association
https://www.kidneycancer.org

Midwest Nursing Research Society
https://mnrs.org/

National Institute of Nursing Research
https://www.ninr.nih.gov/

Society of Clinical Research Associates
https://www.socra.org/