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

Consortium Development Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-KCRP-CDA

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), December 20, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, January 4, 2018
- **End of Application Verification Period:** 5:00 p.m. ET, January 9, 2018
- **Peer Review:** February 2018
- **Programmatic Review:** April 2018

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

The KCRP's vision is to eliminate kidney cancer through collaboration and discovery. The KCRP's mission is to promote rigorous, innovative, high impact research in kidney cancer.

II.B. Award Information

The KCRP seeks to promote a major multi-institutional clinical effort conducted by leading kidney cancer researchers. This effort will be executed through two separate award mechanisms, the Consortium Development Award in FY17 and the anticipated Consortium Award in FY19.

Applications for the FY17 Consortium Development Award are being requested in this Program Announcement. The Consortium Development Award is a clinical trial infrastructure mechanism that provides support to create a Coordinating Center and to establish the necessary collaborations at potential Clinical Trial Sites for the development of a multi-institutional kidney clinical effort relevant to active duty Service members, Veterans, other military beneficiaries, and the American public. ***The goal of the Consortium Development Award is the establishment of the consortium infrastructure for future multi-institutional clinical trials.***

The eligible applicants of the FY17 Consortium Development Award are expected to submit an application to compete for the Consortium Award anticipated to be offered in FY19. The KCRP expects to fund one FY17 Consortium Development Award, depending on the number and the quality of applications received. The KCRP reserves the right to open the FY19 Consortium Award to all eligible applicants that meet the requirements of the anticipated FY19 Consortium Award, and/or to re-release the Consortium Development Award in FY19 if the goals of the FY17 Consortium Development Award are not met.

Consortium Description: The consortium must be a geographically dispersed coalition, including a Coordinating Center and at least three Clinical Trial Sites. All Clinical Trial Sites will be responsible for working collaboratively and providing available research resources to the consortium. The Consortium Director, i.e., the Principal Investigator (PI) of the Coordinating Center, must have a proven track record of leadership and the scientific ability to direct and

oversee the overall research effort. The Consortium Development Award will support a strong collaboration of clinicians and researchers to build the overarching structure of a clinical consortium. The PI and the co-PIs in the consortium should be clinicians and scientists who have made significant contributions to the field of kidney cancer research. Clinical infrastructure development includes (but is not limited to) establishing appropriate collaborations, outlining an administrative management plan, developing research management and communication plans, and devising and implementing an intellectual property plan.

By the end of the award, the infrastructure should be in place and the mechanics of a clinical consortium initiated to maximize the use of resources and standardization of procedures, and to minimize unnecessary duplication among consortium members; for example, experimental techniques, databases, models, antibodies, biomarker tools, phenotyping processes, etc., should be shared resources for all consortium members. The goal is for the consortium to function as a unit rather than as a collection of different sites, with unified processes pertaining to ethics review, contract management and data sharing. The Coordinating Center and the Clinical Trial Sites should have all regulatory, material, and intellectual property agreements in place by the end of the award. Any delays should be well documented and justified with a mitigation plan in place to be considered for funding under the FY19 Consortium Award. Plans to expand to additional Clinical Trial Sites should be in place by the end of the Consortium Development Award.

Coordinating Center: The Coordinating Center, in addition to functioning as a Clinical Trial Site, will serve as the consortium information and planning nexus, providing administrative, operational, and data management support services to implement consortium studies in a timely manner. The Coordinating Center must be a Clinical Trial Site for the future multi-institutional clinical trials.

Key Aspects of the Coordinating Center:

- Experience in establishing multi-institutional collaborations.
- Facilitate consortium-wide communications to optimize and accelerate research progress; communication between and among consortium members is essential to realizing the consortium's objectives.
- Provide effective, coordinated plans that integrate and optimize the research and collaborations within the consortium.
- Development of standard operating procedures.
- Other responsibilities to include: study coordination, study management and monitoring, regulatory coordination, data collection procedures and monitoring, data management and statistics, and intellectual/material property coordination.

Principal Investigator: The PI on the application will be the Consortium Director and the PI for the Coordinating Center. The PI should have a proven track record of leadership and scientific ability to direct and oversee a multi-institutional clinical trial effort. As the PI is

responsible for the day-to-day management of the consortium, the PI is expected to commit an appropriate level of time and effort to direct and manage a project of this magnitude.

Clinical Trial Sites: The co-PIs from the different Clinical Trial Sites should contribute unique research resources and expertise to the consortium. Collaborations established through the development of the consortium should be complementary and should maximize the use of resources and minimize unnecessary duplication among consortium members. For example, experimental techniques, patient accrual, databases, anatomical samples, etc., generated at a Clinical Trial Site should be centrally managed and made available as shared resources for all consortium members. Core facilities for areas of expertise may be established at select Clinical Trial Sites. Clinical Trial Sites, as well as the Coordinating Center, should demonstrate access to an appropriate kidney cancer patient population and/or clinical samples. The co-PIs for the different Clinical Trial Sites should have a proven track record of collaboration and the clinical knowledge to lead clinical trials within a multi-institutional research effort. Each co-PI will be responsible for the day-to-day management of an individual Clinical Trial Site. Data and materials generated from the Clinical Trial Sites should be made available as shared resources. Management plans for sharing of resources and data should be clearly explained in detail. Each co-PI is expected to commit an appropriate level of time and effort to direct and manage a Clinical Trial Site.

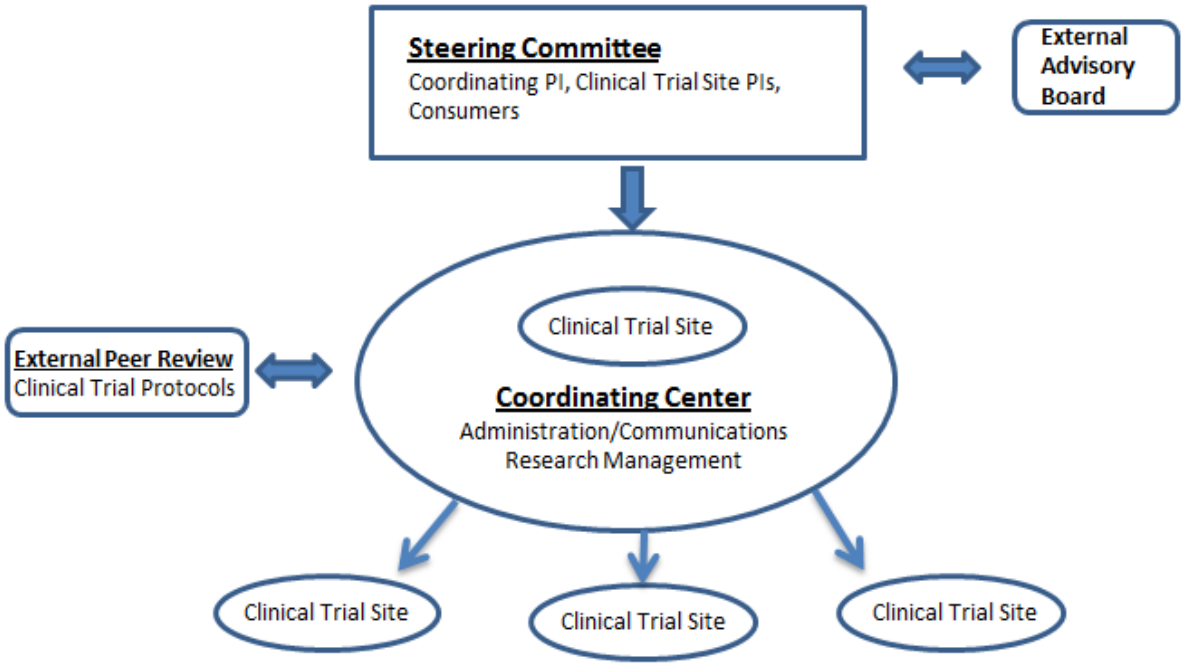
The Coordinating Center will be responsible for coordinating and funding an external scientific peer review of clinical trial protocols proposed for funding at all sites during the future Consortium Award. The Coordinating Center will provide a plan for development and implementation of protocols, external peer review, and prioritization of clinical trials. The results of each peer review will be submitted to the KCRP for assessment. Leveraging of funding and resources from additional sources, including industry, private sector, and other Federal organizations, is encouraged.

Steering Committee: The consortium will establish a Steering Committee, to include the co-PIs from each Clinical Trial Site, the PI from the Coordinating Center, and consumer advocates. The consumer advocates must be kidney cancer patients, or caretakers for someone with kidney cancer, and possess a high level of familiarity with current issues in kidney cancer research. The consumer advocates' role in the committee should be independent of their employment with a participating institution. During the consortium's period of performance, the Coordinating Center PI will chair the Steering Committee. The Steering Committee will meet regularly to monitor the status of ongoing consortium studies and to review progress toward establishment of Clinical Trial Sites. The Steering Committee will be responsible, in coordination with the Coordinating Center, for developing standard operating procedures that will be adopted for consortium studies. The Steering Committee may establish working groups or other scientific committees to ensure successful operation of the consortium.

Oversight of the Consortium Development Award: An External Advisory Board (EAB) composed of kidney cancer researchers who are not involved with the consortium, KCRP Programmatic Panel members, and USAMRMC representatives will provide administrative and scientific guidance to the Grants Officer's Representative (GOR). The EAB Chair and a representative from USAMRMC will be invited to regular meetings of the Steering Committee and must be provided agendas and minutes for these meetings. The Coordinating Center PI and

Clinical Trial Site co-PIs must present written and oral briefings to the EAB and USAMRMC staff at semi-annual 1-day meetings in the National Capital Region. Based on these reports and presentations, the GOR, with input from the EAB and USAMRMC staff, will evaluate progress, provide feedback, and recommend to the USAMRAA Grants Officer actions to be taken as needed to facilitate the success of the Consortium Development Award toward a fully functioning consortium. The Coordinating Center PI will also be required to submit quarterly progress reports and a final comprehensive written report of the consortium's accomplishments to the USAMRMC. Figure 1 presents a chart showing the structure of the expected consortium.

Figure 1. General Consortium Structure



The Coordinating Center plus three Clinical Trial Sites (the Coordinating Center may count as one of the three Clinical Trial sites) must submit a single application for the FY17 Consortium Development Award. A single award will be made to the Coordinating Center, which will provide management oversight and funding, via subawards or other appropriate instruments, to the Clinical Trial Sites. Award funds are to be used to support the Coordinating Center's efforts and the consortium development-associated activities at each Clinical Trial Site.

The anticipated total costs budgeted for the entire period of performance for an FY17 KCRP Consortium Development Award will not exceed $1M. Refer to Section II.D.5, Funding Restrictions, for detailed funding information**.**

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (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 Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition

to the centralized Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. In accordance with 32 CFR 219.114(a)-(b), multiple site clinical trials must all be reviewed and approved by a central IRB. After approval by the central IRB, all clinical trials must be approved by the DoD USAMRMC ORP prior to initiation of recruitment. 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.

Clinical trials will not be supported by the FY17 Consortium Development Award, but clinical trial protocol development is allowed. A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

Use of Military and VA Populations and/or Resources: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for demonstrating such access. If possible, access to target active duty military and/or VA patient population(s)/resource(s) should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest-ranking person with approval authority, for studies involving active duty military Service members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research or by advertising to the general public.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

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

II.C.1.b. Principal Investigator: An eligible PI (who will be the Consortium Director) will be a faculty member at or above Assistant Professor (or equivalent) level. PIs should have a strong background and expertise in kidney cancer and the biographical sketches should reflect this expertise. PIs of proposed Clinical Trial Sites should have a strong background and expertise in kidney cancer and the biographical sketches should reflect this expertise. The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

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 http://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 is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submitted by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

The multifunctional web-based system eBRAP 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.

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at https://eBRAP.org.

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section 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*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Application Submission: Full applications must be submitted through the online portals as described below.

***Submitting Extramural Organizations*:** Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP may be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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 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 deadline.

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

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed 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 may result in delays in 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.

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

PIs and organizations 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 PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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**

- **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 (R&R) 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 (R&R) 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 PIs 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.

FY17 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.

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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**
    - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the proposed consortium development effort. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Tab 6 – Submit Pre-Application**

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

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

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 (http://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, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-KCRP-CDA from Grants.gov (http://www.grants.gov).	Download application package components for W81XWH-17-KCRP-CDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application 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 Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R 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	
Submit package components to Grants.gov (http://www.grants.gov). 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.	**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 "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.

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, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller or equivalent Business Official and PI will receive an 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, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information	
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 organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

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 (R&R) 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 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 qualifications of the consortium member institutions and personnel, and plans for the development of key features of the consortium, using the following general outline:

    - Provide a description of the projected consortium organization. Include key participants at the Coordinating Center and the Clinical Trial Sites, and their projected contributions. Describe previous experience and accomplishments of the PI (Consortium Director) related to the design, administration, and management of multi-institutional research projects.

    - Describe the research and communication plan for developing the consortium. Include plans for assessing the performance of each Clinical Trial Site.

    - Outline the development of resource and data sharing plans, and the development of standardized methods across all sites including data entry and storage.

    - Describe experimental strategies to optimize standardization of procedures across multi-institutional sites.

    - Describe plans for centralized sample storage and access.

    - Describe plans for streamlining the process required to initiate clinical trials across sites (e.g., unified scientific and IRB reviews).

- Describe the clinical research approach for the consortium. Include a discussion of the background and scientific rationale behind the consortium's focus as well as the potential impact the consortium's research could have on kidney cancer.

- Discuss innovative methods, collaborations, therapies, etc., that will be incorporated into the proposed consortium.

- Describe the personnel and their expertise to accomplish the establishment of a consortium.

- Discuss plans to establish the Steering Committee and the external peer review.

- Include a brief description of the available resources and how unnecessary duplication of resources among consortium members will be minimized.

- **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. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested 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). The inclusion of URLs to references is encouraged.

  - 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 publications 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 (no page limit): 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.

  If a military/VA investigator is included in the application, letters from the military/VA investigator's immediate supervisor and/or Commander must be provided that demonstrate a commitment to allow the military/VA investigator to participate in the project.

- Letters of Collaboration (if applicable) (two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

- **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.

  Technical abstracts should be written using the outline below.

  - **Background:** Present the ideas and reasoning behind the proposed consortium. Describe the clinical and translational research outcomes upon which the study is founded.

- **Objective:** State the objective to be reached. Describe the overall goals of the consortium development. Describe the clinical goals to be realized once a consortium is established.

- **Collaboration:** Describe how the project depends on the unique skills and resources of the Coordinating Center and Clinical Trial Sites. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the clinical collaboration will maximize the use of existing resources and minimize unnecessary duplication.

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

  Lay abstracts should be written using the outline below. Do not duplicate the technical abstract. Avoid overuse of acronyms and abbreviations, if possible. Describe the proposed project by including the following elements in plain language.

  - 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 proposed consortium. What types of patients will it help, and how will it help them? What are the potential clinical outcomes, benefits, and risks? What is the projected time it may take to achieve a patient-related outcome? What are the likely contributions of this consortium to advancing the vision of the KCRP to eliminate kidney cancer through collaboration and discovery?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Consortium Development mechanism, use the SOW format example titled "Statement of Work (SOW) Generic Format." The SOW must be in PDF format prior to attaching.

  The SOW should include a list of major tasks that support the proposed specific aims, followed by an outline of subtasks 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.

Briefly state the steps that will be taken to integrate the Coordinating Center and the Clinical Trial Sites to form a coherent research consortium.

- Indicate the steps for initiating a management and communication plan between the Coordinating Center and the Clinical Trial Sites.
- Indicate timelines for initiating standard operating procedures among the Coordinating Center and the Clinical Trial Sites. Include any strategies to optimize standardization of procedures.
- Indicate the procedures to initiate intellectual property and material transfer agreements.
- Include other relevant milestones necessary to develop clinical trials for the proposed consortium.

Briefly describe the resource sharing plan.

Include tasks for all individual Kickoff, EAB meetings, and for the establishment of external peer review, and Steering Committee.

Outline a plan for cross-institutional development of clinical trial protocols and statistical measures.

Include timelines for establishing the Steering Committee, EAB, and external peer review panels to review clinical trial protocols.

- **Attachment 6: Collaboration Plan (two-page limit):** Upload as "CollabPlan.pdf."
  - Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all organizations participating in the project.
  - Describe each team member's role and responsibilities, as well as intellectual contribution to the proposed consortium. Describe how the project depends on each investigator's unique skills. Provide the time commitment for the PI and co-PIs. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
- **Attachment 7: Transition Plan (two-page limit):** Upload as "Transition.pdf." Describe the methods and strategies proposed to move the proposed consortium to the next phase of development at the end of this award, i.e., toward an expansion of the consortium and the initiation of clinical trials. The transition plan should include a schedule and milestones for transitioning from infrastructure development to active clinical trials by leveraging potential funding resources. It should also include a description of plans and potential funding sources to continue clinical research beyond the FY17 Consortium Development Award if the applicant is not awarded an FY19 Consortium Award or in the event that FY19 KCRP funding is not available.

- **Attachment 8: Impact Statement (one-page limit):** Upload as "Impact.pdf." State explicitly how the proposed work addresses a critical problem in kidney cancer. Describe the pathway to making an impact on kidney cancer research and/or patient care and explain how the specific research goals, if achieved, would fit into that pathway.

- **Attachment 9: Clinical Trial Development Statement (three-page limit):** Upload as "Clinical.pdf." Describe the rationale for the proposed clinical trials. Provide a description of the intervention and the endpoints to be measured. Provide detailed plans for initiating the future clinical studies including FDA IND/IDE application submission plans (if applicable). Indicate the access to the study population and recruitment plans. Describe potential challenges and alternative strategies, where appropriate.

- **Attachment 10: Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s) (e.g., Human/Animal Anatomical Substances, Databases), *if applicable* (one-page limit per letter):** Upload as "Access.pdf." If the proposed research plan involves access to active duty military and/or VA patient population(s) or resource(s), include a letter of support, signed by the lowest-ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s).

- **Attachment 11: Use of Hazardous Chemical or Biological Agents, *if applicable* (no page limit):** Upload as "Hazardous.pdf." The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information, such as proof of registration of the agent(s) with the U.S. Centers for Disease Control and Prevention, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from Government sites issuing any agent(s). Indicate whether agents to be used will be purchased commercially, and, if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

- **Attachment 12: DoD Military Budget Form(s), *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 the DoD Military Budget Form, 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 and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  Research & Related Senior/Key Person Profile (Expanded): 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.

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

  - 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.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

  Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

  R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload toGrants.gov as Attachment 12. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

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

Applicant organizations and all subrecipient 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's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 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.

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

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. 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 retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***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 Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

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

The anticipated total costs budgeted for the entire period of performance will not exceed **$1M**. 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 **$1M** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

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

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, funding must be requested for:

- ***Kickoff Meeting:*** Travel costs for the Coordinating Center PI and the Clinical Trial Site co-PIs to initiate the Consortium Development Award project and meet with the USAMRAA Grants Officer, the USAMRMC ORP representative, and the CDMRP KCRP GOR and Science Officer. For planning purposes, it should be assumed that the meeting will be held in the National Capital Region. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- ***External Advisory Board Meetings:*** Travel costs for the Coordinating Center PI and the Clinical Trial Site co-PIs to disseminate project results at up to three KCRP EAB meetings. For planning purposes, it should be assumed that the meetings will be held in the National Capital Region. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary

- Research supplies

- Clinical research costs associated with development of multi-institutional clinical trials

- Meetings and teleconferences among participating investigators to develop the consortium, including applicable travel costs

- Other costs associated with planning and developing the consortium collaborations, clinical trials, and resources

- Travel costs for up to four investigators to travel to one scientific/technical meeting per year

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). 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 fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund 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.4, 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.4***.

The CDMRP expects to allot approximately $1M of the $10M FY17 KCRP appropriation to fund approximately 1 Consortium Development Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Consortium Structure**
    - Whether the consortium includes a Coordinating Center and Clinical Trial Sites with named scientists and/or clinicians who have made significant contributions to the field of kidney cancer research.
    - How well the proposed infrastructure development activities include establishing appropriate collaborations, outlining an administrative management plan, developing a research and communication plan, and devising intellectual/material property plans.
    - How well it is shown that the Coordinating Center and Clinical Trial Sites will maximize sharing of resources and minimize unnecessary duplication of resources.
    - How appropriately the consortium's research resources support the proposed consortium objectives.
    - How well any experimental strategies proposed will optimize standardization of procedures across all sites.
    - How effectively the coordination plans to integrate and optimize the research and collaborations will lead to successful development of the proposed consortium.

- Whether the plans for coordination of regulatory procedures and documentation, data collection procedures, and monitoring are feasible and clearly defined.

- How well the plans for data management and statistics support a multi-institutional consortium.

- To what degree the proposed collaborations and other resources for providing continuity of development are established and/or achievable.

- **Clinical Trial Development**

  - How well the application supports the rationale for the proposed clinical trials with definitive plans for standardized methodology, resources, and procedures over all sites.

  - How well the application describes potential access to the study population.

  - To what degree the potential challenges and alternative strategies for the proposed clinical trials are described.

  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- **Impact**

  - How well the proposed consortium will address a critical problem and/or patient care in kidney cancer.

  - To what degree the proposed consortium goals, if achieved, will contribute to advancing the field of kidney cancer research and/or patient care.

- **Transition Plan**

  - To what extent the methods and strategies proposed to move the consortium to the next phase of development, i.e., toward an expansion of the consortium and the initiation of the clinical trials, are feasible.

  - Whether the schedule and milestones for transitioning from infrastructure development to active clinical trials are achievable.

  - Whether a description of plans and potential funding sources to continue clinical research beyond the FY17 Consortium Development Award if the applicant is not awarded an FY19 Consortium Award or in the event funding is not available from the FY19 KCRP is included and is feasible.

- **Personnel**

  - How well the PI's (Consortium Director's) qualifications and experience demonstrate appropriate expertise in the design, organization, and management of multi-institutional research projects.

- The degree of experience the PI and each co-PI have to function as a partner in the proposed collaborative project.
- The extent to which the PI and each co-PI, including the military or VA investigator (if applicable), will substantially contribute to the development and implementation of the consortium development plans and to the reciprocal flow of information.
- To what degree the levels of effort are appropriate for the successful completion of the development of a consortium.

The following criteria will not be individually scored, but may impact the overall evaluation of the application.

- **Environment**
  - To what degree the scientific environments are appropriate for the proposed research.
  - To what degree the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what degree the quality and extent of institutional support are appropriate.
- **Budget**
  - Whether the maximum **total** costs are equal to or less than the allowable maximum total costs as published in the Program Announcement.
  - Whether the budget is appropriate for the proposed effort.
  - Whether there may be significant overlap with existing or pending awards of the PI and co-PIs.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 KCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism

- Collaboration
- 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 of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP, and KCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***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 http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement 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 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 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 (currently $150,000) 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, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself 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 (DoDGAR), 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 will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative 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. 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). Substantial involvement may include 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.

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

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.

Intramural Organizations: Awards 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 managers (RM).

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

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

Changes in PI and co-PIs 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 DoDGAR found in 32 CFR, Chapter 1, 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 USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations 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. Annual progress reports as well as a final progress report will be required.

Quarterly technical progress reports will be required.

In addition to written progress reports, in-person presentations will be required.

In addition to written progress reports, Annual Award Charts will be required. For the Consortium Development mechanism, use the format example titled, "Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

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 Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

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 20170516e. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

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 FY17 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 FY17 KCRP Programmatic Panel members can be found at http://cdmrp.army.mil/kcrp/panels/panels17***.
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- 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 FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review 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.

- Applications proposing funds for the support of a clinical trial may be withdrawn (funds for the development of clinical trial protocols etc. are allowed).

- Applications where the Coordinating Center PI or the Clinical Trial Site co-PIs do not meet the eligibility requirement may be withdrawn.

- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these 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."	
	Collaboration Plan: Upload as Attachment 6 with file name "CollabPlan.pdf."	
	Transition Plan: Upload as Attachment 7 with file name "Transition.pdf."	
	Impact Statement: Upload as Attachment 8 with file name "Impact.pdf."	
	Clinical Trial Development Statement: Upload as Attachment 9 with file name "Clinical.pdf."	
	Letters Confirming Access to Target Military or VA Patient Population(s) or Resource(s): Upload Attachment 10 with file name "Access.pdf," if applicable.	
	Use of Hazardous Chemical or Biological Agents: Upload Attachment 11 with file name "Hazardous.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 12 with file name "MFBudget.pdf," if applicable.	

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

APPENDIX 1: ACRONYM LIST

CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGAR	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
FY	Fiscal Year
HRPO	Human Research Protection Office
IRB	Institutional Review Board
KCRP	Kidney Cancer Research Program
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OMB	Office of Management and Budget
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code