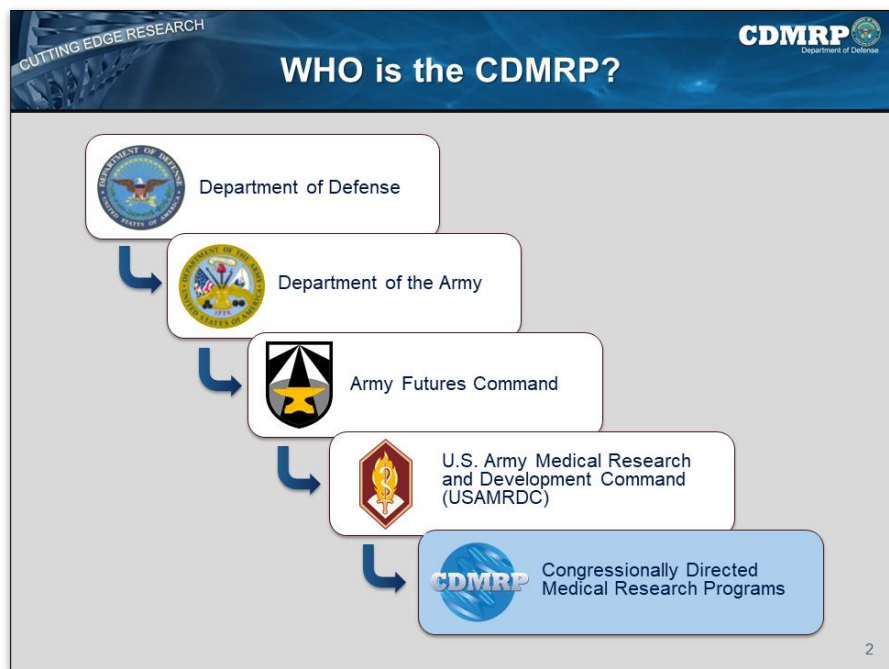


Meet Our Presenters:

Dr. Donna Kimbark: Dr. Kimbark received her PhD in Molecular Biology in Cancer Therapeutics. She has been the Program Manager for the Peer Reviewed Cancer Research Program (PRCRP) at the CDMRP for the past 11 years. BCAN is really delighted to have Dr. Kimbark for the second year to give you the information you need to consider applying for some of these funds.

Dr. Kimbark:

I'm the Peer Review Cancer Research Program Manager. I've been with the CDMRP for 17 years now and I started with the PRCRP as it was started in FY 09. First of all I thought what we would do is talk a little bit about what the CDMRP is. I know that some of you may know what the Congressionally Directed Medical Research Program is, I understand that, but some people it's just a new concept. So I just wanted to give you a heads up of what the CDMRP is. We are part of the Department of Defense. We sit underneath the



Department of the Army. We are part of the Army's Medical Command and we actually sit at Ft. Dietrich up in Maryland.

A little bit about the CDMRP, we have grown substantially over the years. When I first started at CDMRP in 2002, I think we had like six programs total. I think now we have about 30 programs and we manage over a billion dollars, yes that's with a B, a billion in dollars of research funds a year. You can see some of our current programs on the bottom of that slide. From alcohol and substance abuse to Lupus to Parkinson's to the Peer Review Cancer Research program. We have some additional programs that we also support that are core funds.

```

graph TD
    A[Congressional Appropriation] --> B[Receipt of Funds]
    B --> C[Vision Setting]
    C --> D[Funding Opportunities Released]
    D --> E[Proposal Receipt]
    E --> F[Peer Review]
    F --> G[Programmatic Review]
    G --> H[Approval of Commanding General]
    H --> I[Negotiations]
    I --> J[Award Execution 1-5 years]
    J --> K[Proposal Receipt]
    
```

About CDMRP

◆ CONGRESSIONAL PROGRAMS

- Manages extramural research programs directed by Congress
- Started in 1992 with a focus on breast cancer research; currently includes over 30 research programs
- Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects
- Unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers
- Funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

◆ DoD PROGRAMS

- Provides support to Program Area Directorates (PADs)/Joint Program Committees (JPCs) for managing extramural and intramural research portfolios to advance their missions

◆ DIRECTOR

- COL Stephen Dalal

FY20 PROGRAMS:

- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Breast Cancer Semipostal
- Combat Readiness
- Chronic Pain
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness
- Hearing Restoration

- Joint Warfighter Medical
- Kidney Cancer
- Lung Cancer
- Lupus
- Melanoma
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Pancreatic Cancer
- Parkinson's

- Peer Reviewed Alzheimer's
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Rare Cancers
- Reconstructive Transplant
- Scleroderma
- Spinal Cord Injury
- Tick-Borne Disease
- Tuberous Sclerosis Complex
- Vision

ADDITIONAL SUPPORTED DOD PROGRAMS:

- Armed Forces Institute of Regenerative Medicine II
- Centers of Excellence
- Defense Medical R&D
- Defense Medical R&D Restoral
- Psychological Health and Traumatic Brain Injury
- Small Business Innovation/Small Business Technology Transfer
- Trauma Clinical

And what's the difference between our current programs and our core fund programs? Our current programs are added to DoD budget by Congress. They decide whether or not we should add these funds.

This was all started in 1992 with a focus on breast cancer research. It was a response to advocates going to the hill and asking for changes unless cancer research was done. And so Congress did this in 1992, and ever since then we've been growing and we hope succeeding.

Congress specifies the specific type of program, and then CDMRP along with experts in the field determines the research strategy and how we're going to competitively select the projects.

We fund high impact innovative medical research projects and one of the things we want to say is that we do not compete with other federal agencies or other agencies that might fund these different topic areas. It's not for us to do that. We're here to meet those unmet gaps. To fill in where we need

Vision and Mission

Vision

Transform healthcare for Service Members and the American public through innovative and impactful research

Mission

Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans and the American public

to fill in. Let's just say that CDMRP is like the Special Forces. We go and we do those areas that have unmet gaps and needs for that community.

Dr. Kimbark:

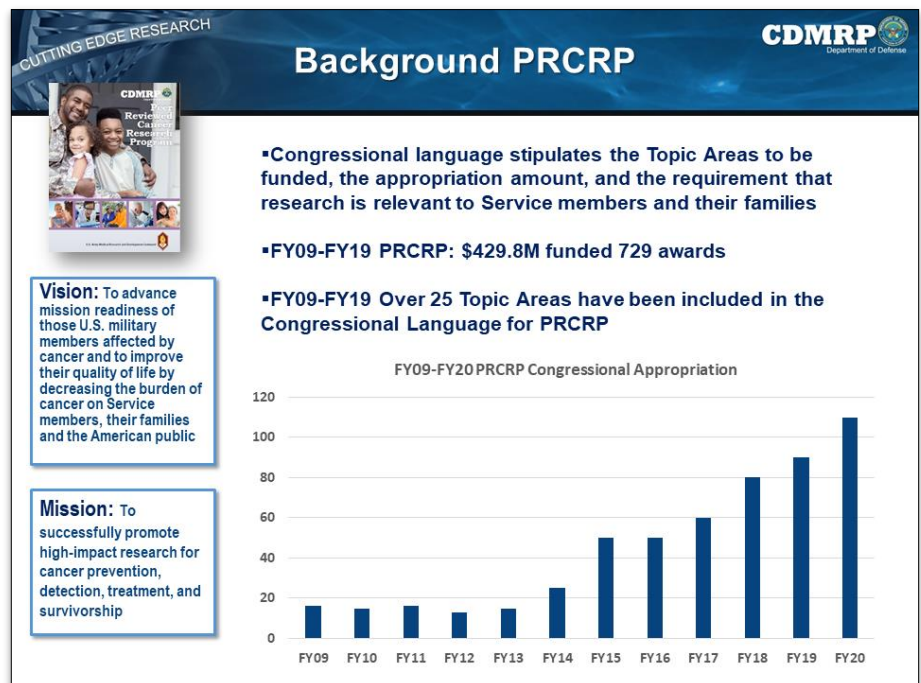
Our vision is to transform healthcare for Service Member and the American public through innovative and impactful research. How do we do that? We do that by funding ground breaking research. And our hope is that by doing that and by responsibly managing collaborative research, that we will help discover, develop and deliver healthcare solutions for Service members, Veterans and the American public.

Let me tell you a little bit about the Peer Reviewed Cancer Research program. This is really my baby. It started in Fiscal Year 09. I've been the Program Manager since then. Through Fiscal Year 18, we've had almost \$340 million appropriated for the Peer Reviewed Cancer Research program. FY19, this year, is \$90 million. \$90 million. It's the highest we've ever had. Just to give you a feeling of what that means, in FY09 we had four topic areas and we had \$16 million. Now we have \$90 million.

So let me tell you a little bit about the history of Peer Reviewed Cancer program. It has Congressional language that stipulates the topic areas to be funded. That means that this is a peer Reviewed Cancer research program that specific topic areas, specific types of cancers are going to be funded under this program.

We have other programs like breast cancer and lung cancer and they only fund those types of cancer. Peer Reviewed Cancer program stands out and differentiates itself from the other cancer programs that are managed by the CDRMP because of the fact that we have multiple topic areas. And so we have a juggling job to do here.

So, let me go ahead and say for this year we have our largest appropriation of \$90 million. To give you some respective of how this has changed, give you a little bit of idea of how this has changed throughout the years, in FY09, we had four topic areas and we had



\$16 million. Now we have \$90 million for FY19. That's the largest appropriation we have ever had.

Congressional language also stipulates the topic areas to be funded. That means that the Peer Reviewed Cancer Research program as specific types of cancer that will be funded that is directed by Congress. I do not sit in my office and decide which topic areas are going to be funded. Actually, Congress tells us that. It's very different then some of the other cancer programs that are managed by the CDMRP.

We have the appropriation amount that Congress dictates as well as the requirements that research is relevant to Service members and their families. I will be talking a little bit more in depth on that and how you should approach that part of the requirement as we go through the Webinar today.

Over the last 10 years, the PRCP has funded over 24 topic areas that have been included in the Congressional language. Our vision is to advance mission readiness of the U.S. Military members affected by cancer and to improve quality of life by decreasing the burden of cancer on Service members, their families and the American public.

Let's get into a little bit about our Congressional language for this year. Our Congressional language this year stipulates 15 topic areas for the Peer Reviewed Cancer Research program. From bladder cancer all the way down to stomach cancer. You'll notice that rare cancers is in red. That's because it's a new topic area this year. Bladder cancer's at the top of the list here.


Dr. Kimbark:

I just wanted to talk a little bit more about some of the topic areas and give you some heads up about what you should do with your application.

First of all, the applicants must address at least one of the topic areas as directed by Congress. You can't just decide that you're going to pick out some other cancer and I don't suppose anyone here would do that but you're going to be, you know, mainly looking at bladder cancer.

The funds may not be used for research into breast, prostate, ovarian, kidney, melanoma or lung cancer. All of these have their own programs that are managed by the CDMRP, so we must not use our funds for any of these.

Research progress should be relevant to Service members and their families. One other thing, when you are about to decide what your topic area is going to be, because that's one of the drop downs that you



The slide is titled "Strategic Guidance Congressional Language: FY20 Topic Areas" and features the CDMRP Department of Defense logo in the top right corner. It lists 15 FY20 Topic Areas in a bulleted format. To the right of the list are four blue boxes containing key requirements and restrictions. The first box states that applicants must address at least one of the topic areas as directed by Congress. The second box lists exclusions: funds may not be used for research into breast, kidney, lung, pancreatic, prostate, ovarian, rare cancers, or melanoma. The third box clarifies that the inclusion of the Rare Cancer Research Program does not prohibit PRGRP from funding cancers or cancer subtypes that may be rare by definition. The fourth box states that research progress should be relevant to Service members and their families.

CUTTING EDGE RESEARCH

Strategic Guidance
Congressional Language: FY20 Topic Areas

CDMRP
Department of Defense

FY20 Topic Areas

- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- Esophageal cancer
- Head and Neck cancers
- Immunotherapy
- Liver cancer
- Mesothelioma
- Metastatic cancers
- Neuroblastoma
- Pediatric, adolescent, and young adult cancers
- Pediatric Brain Tumors
- Stomach Cancer

Applicants must address at least one of the Topic Areas as directed by Congress

Funds may not be used for research into breast, kidney, lung, pancreatic, prostate, ovarian, rare cancers, or melanoma

The inclusion of the Rare Cancer Research Program shall not prohibit PRGRP from funding cancers, or cancer subtypes that may be rare by definition

Research progress should be relevant to Service members and their families

will be looking at, you should always, always, always pick what's the most relevant topic area. And that is so you're going to be put on the correct Peer Review panel.

And that next slide is going to talk about another requirement. You had one requirement of picking bladder cancer, for instance, as your topic area. The other requirement is going to be that you have to have relevance to military focus area.

We have two different military focus areas and this is environmental or exposure risk factors that are associated with cancer or mission readiness. Environmental exposure such as ionizing radiation, chemicals, infectious agents, environmental carcinogens that might lead to an increase risk of developing cancer by either a Service members, their families, or the American public is something that you really need to address and link it back to the military health system.

The other one is mission readiness.

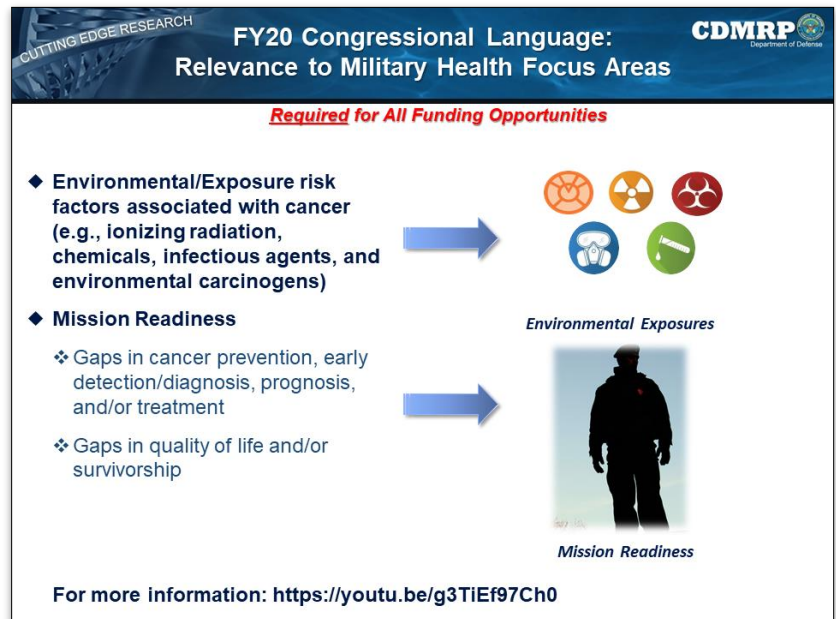
We really like to talk about this one as gaps in the cancer care spectrum.

From prevention to screening, early detection, diagnosis, treatment and/or survivorship that may have a profound impact on the health and well-being of Service members, Veterans, and their beneficiaries.

We did try to take a little bit of time in our program announcements this year to explain this a little bit more in depth. I'm not going to go into that, but I do want to say mission readiness is not always about just the Service member but also about the support that the Service member might have family, the friends, and so on. If the family of a Service member gets sick with cancer, that Service member is no longer mission ready because that Service member may be pulled out of a deployment. May be pulled out of the mission. May not be able to transfer to a new area in order to stay where that family member is getting treatment. So let's remember that it's not just about the Service member but about the families as well and Veterans.

Okay, FY09 through FY17, the PRCRP Investment per Topic Area is shown here. You'll see that bladder cancer has a very small cut in that pie of 3%. You're like, oh why is that only 3%? Well, bladder cancer only started to be included in the PRCRP in FY16. So in FY16 and FY17, that bladder cancer was able to get about 3% of the total pie from FY09 through FY17. We still have a very large portion if you just do FY16 and 17.

So you can see that there's many different types of cancers that have been part of the Peer Reviewed Cancer Research program over the years. Like melanoma and other skin cancers was with the Peer Reviewed Cancer Research program for 10 years. It is no longer with us. It has its own program. It was a large competitor and it takes a large part of that pie. So now it's gone. There's a gap there for people to fill in so that's really an opportunity for all of the different topic areas.



Dr. Kimbark:

I'm going to talk a little bit about the application statistics for bladder cancer. For FY16, we had eight awards made for bladder cancer with \$5.5 million. We had a good number of applications come in; preapplications and full applications.

In FY17 we only had four awards with \$2.8 million. Why was that? I kind of feel like that one of the reasons was is because we didn't have this great opportunity to give this webinar. We didn't have it that year in FY17.

In FY18, we ended up with 14 awards being made in the bladder cancer topic area with \$9.3 million invested. It was the highest number. Of all the different topic areas we had last year, we had 17 topic areas with \$80 million for appropriation and bladder cancer had the most invested.

So, that's a great growth for bladder cancer so let's keep it up.

The next slide, we're going to talk a little bit about our funding opportunities. I know that all these statistics might be encouraging and exciting and all of that, but really the end run around you really want me to say is how to find these funding opportunities and what those funding opportunities are.

This is a slide that shows you three different places that you can find our funding opportunities online. At the CDMRP website. Go there, look for funding opportunities. Also our E grant website, which I'm going to talk a little bit about today. This is our portal where you start your pre application. So that's somewhere where you can get our funding opportunities. And also, go to [Grants.gov](https://grants.gov). You can go to Grants.gov and put our CFDA number in of 12.420 and it will come up with all of the CDMRP funding opportunities that are open at that time.

So what are our funding opportunities for Peer Reviewed

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

FY16-FY20 PRCRP Bladder Cancer

◆ **Background**

◆ **Research in Bladder Cancer Highlights**

❖ FY16-FY18 PRCRP funded 28 bladder cancer awards totaling \$17M (funding rate 22%)

❖ FY19 PRCRP funded 9 bladder cancer awards totaling \$5.9M (funding rate 22%)

Investigator/Org	Type of Award	Title	Outcomes
Matthew Galsky, M.D.; Icahn School of Medicine at Mount Sinai	Idea Award with Special Focus	Circulating Tumor Cell-Based Patient-Derived Xenograft Models of Metastatic Bladder Cancer as a Platform for Development of Novel Therapeutic Approaches	Dr. Matthew Galsky Dr. Josep Domingo-Domenech (Thomas Jefferson University) developed a new collection of paired patient-derived xenograft mouse models derived from patient circulating tumor cells before treatment initiation and then as disease progresses
James McGrath, Ph.D.; University of Rochester	Idea Award with Special Focus	Nanomembrane Capture and Characterization of Cancer-Derived Exosomes in Urine	Dr. McGrath is developing a novel platform to capture exosomes from small volumes of unprocessed biofluid as a source for biomarkers for bladder cancer. The ultimate goal is to distinguish between exosomes derived from uroepithelial carcinoma from those derived from benign tissues. Membranes show promise.
Dan Theodorescu, M.D., Ph.D.; Cedars-Sinai Medical Center	Impact Award	Targeting the Regulation and Actions of Telomerase Reverse Transcriptase (TERT) in Bladder Cancer	Telomerase Reverse Transcriptase (TERT) is a key component of telomerase, the complex that keeps chromosome ends from shortening and leading to cellular senescence. Overexpression is linked to cisplatin and doxorubicin resistance; identify and synthesize small molecule inhibitors that could reduce TERT expression, and to develop drug combinations that will make the TERT-overexpressing cancer cells more vulnerable to therapy

9

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

Finding Funding Opportunities

CDMRP

https://cdmrp.army.mil

2018 Program Funding Opportunities

Latest News

For Investigators

Open Funding Opportunities

Submit your application

How to Apply

Grants.gov

https://ebrg.org

SEARCH GRANTS

CFDA 12.420

Grants.gov "Search Grants"

10

Cancer Research program? Let's go to the next slide and we can see some of the ones that are important for us to take a look at.

These are three of our big funding opportunities. The Idea Award with Special Focus, the Impact Award, and the Translational Team Science Award. These are what I call my pre proposal required funding opportunities and I'm going to talk about what that means in a moment.

The Ideal Award with Special Focus has been around for a while. If you've applied to our program before, you might know a little bit about this. This is for all

researchers at the faculty level appointment are eligible. It's really supporting your high risk, high gain type of research. That innovative idea. You don't want it to be that incremental advance. You don't want it to be oh I studied this in this cancer, now I'm going to schedule it in bladder cancer. No, that's not what we're looking for. We're looking for some innovation. Some really some out of the box ideas here.

We do have a special focus on military health. It's not any different from what I just already talked to you about so you're good to go there. They have preliminary data is not required here. You don't have to put preliminary data, but a strong rationale and background is important. The direct costs is \$400k over two years.

The next award mechanism we have is our Impact Award. Our Impact Award is for Assistant Professors or above are eligible. Really what we're looking for here is more mature science. Maybe you had an Idea Award a couple years ago and now you have some really good preliminary data that you think you can explore and expand and mature that science. That's where the Impact Award comes in. We're really looking to support research or ideas that are specifically focused on a critical scientific or a clinical cancer issue and have the potential to make a major impact in one of those topic areas.

We have clinical trial support is allowed. If you're going to do a clinical trial for something, it's got to be mature enough to support that, but you can go ahead and do some clinical trial work. Preliminary data is required, of course, here. And the direct costs is \$1 million over three years.

Dr. Kimbark: Now our Translational Team Science Award is a very interesting award mechanism because people kind of like ignore it for the other ones. It always has one of the highest rates of funding, usually around 22 to 25% funding rate. So we have an Assistant Professor or above are eligible. Two to three PIs coming together to work as partners. They'll each get their own award to support correlative studies associated with ongoing or completed clinical trials. You can do some clinical trial support. That's

FY20 PRCRP Funding Opportunities Preproposal Required	
Idea Award	Impact Award
<ul style="list-style-type: none">• All researchers with faculty level appointment eligible• Supports innovative, high-risk/high gain research• <u>1 page pre-proposal</u>• Invitation to Submit full application• Emphasis on innovation• Preliminary data not required• Direct costs - \$500k up to 3 yrs.	<ul style="list-style-type: none">• Assistant Professor or above eligible• Support research projects or ideas that specifically focus on critical scientific and clinical cancer issues, have the potential to make a major impact on one of the FY20 PRCRP Topic Areas• <u>2 page pre-proposal</u>• Invitation to Submit full application• Clinical Trial support• Preliminary data required• Direct costs - \$1M over 3 yrs.

okay, but the main focus here should really be those correlative studies. The emphasis is on military health again and preliminary data is required. The direct costs amongst all of the partners, you have to split this amongst all of the partners, is \$1.5 million over four years.

If you go to the next slide please, we have two more funding opportunities. These are letter of intent funding opportunities and I'll describe what that means in just a bit.

CUTTING EDGE RESEARCH
CDMRP
Department of Defense

FY20 PRCRP Funding Opportunities
Letter of Intent

Translational Team Science Award	Behavioral Health Science Award
<ul style="list-style-type: none"> Assistant Professor or above eligible 2-3 PIs partner Supports correlative studies associated with an ongoing, completed trial Areas of Emphasis: <ul style="list-style-type: none"> Interventions to improve QoL Cancer prevention or early detection Clinical Trial support New for FY20: Letter of Intent → letter with topic area stating intent to apply No invitation needed to apply to full application solicitation Preliminary data required Direct costs - \$1.5M amongst the partners over 4 yrs. 	<ul style="list-style-type: none"> New for FY20 Independent investigator with a faculty-level appointment (or equivalent). Supports innovative research Prevention, survivorship, QoL, psychosocial effects related to cancer Supports Pilot Clinical Trial support Letter of Intent → letter with topic area stating intent to apply No invitation needed to apply to full application solicitation Preliminary data required for applications proposing a pilot clinical trial Direct costs - \$1M over 4 yrs.

This is for our earlier, younger investigators. This is our Horizon Award or the Career Development Award. Perhaps you have a pre-doctoral candidate or postdoctoral fellow in your laboratory. The Horizon Award is a great place to start with that. You can be their mentor at a level of Assistant Professor. They do have to do a research development plan is required. They have to put together a plan that's not phoned in. You really should develop that plan with them to show how you're going to mentor them through the steps. And the emphasis here is on impact. We're not looking for innovation here. We're really looking for impact. We don't want risky type of awards here for a pre-doc or a post doc. The preliminary data is not required and it's a direct cost of \$150k over two years.

And finally the Career Development Award. Perhaps you know of an independent investigator within 10 years of their terminal degree. They're ready to go. They're a new Assistant Professor. Maybe they're a Research Assistant Professor or Instructor. They would be considered an independent investigator as long as they can show that they have independent or a laboratory space within someone else's lab. They can still be considered an independent investigator as long as the

CUTTING EDGE RESEARCH
CDMRP
Department of Defense

FY20 Career Development Award
Fellow or Scholar Options

◆ Fellow	◆ VCC Scholar
<ul style="list-style-type: none"> ◆ Independent investigators at or above the level of Assistant Professor or Instructor (or equivalent) and within 7 years after completion of their terminal degree ◆ Career Guide at level of Associate Professor ◆ Supports impactful research ◆ Preliminary data not required ◆ Letter of Intent → letter with topic area stating intent to apply ◆ No invitation needed to apply to full application solicitation ◆ Direct costs - \$400k over 3 yrs. 	<ul style="list-style-type: none"> ◆ Independent investigators at or above the level of Assistant Professor or Instructor (or equivalent) and within 7 years after completion of their terminal degree ◆ Career Guide at level of Associate Professor ◆ Supports Scholars in the unique, interactive virtual cancer center focused on fostering the next generation of independent cancer researchers ◆ Candidate should demonstrate an outstanding level of productivity and potential ◆ Provides intensive mentoring, national networking, and a peer group for junior faculty ◆ Opportunity to network across different cancers, different research disciplines ◆ Letter of Intent → letter with topic area stating intent to apply ◆ No invitation needed to apply to full application solicitation ◆ Direct costs - \$800k over 4 yrs.

institute signs off on it. You cannot, you cannot discount your years as a postdoc in that 10 years but you can discount years spent in a medical residency or family medical leave. The career guide is kind of like a mentor. It should be at the level of an Associate Professor and supports impactful research. Focus here, again, on military health. Preliminary data is not required and the direct costs are \$300k over three years.

So those are our five different funding opportunities. Now what I'm going to go into on our next slide, is to look at how to get through these funding documents and how to get through all the rigamarole.

The first thing is what do the funding documents look like? Most people just look at the one that's on the left side, the program announcement, but you should also look at the one that's on the right side, the general application instructions.

The program announcement itself is going to give you award information, the program description. It's going to tell you what the pieces and parts of the application package that you have to put together from the project narrative to the innovation statement, the impact statement and so on.

The general application instructions will actually go through step by step guide of how to put in your pre-application, how to put in your full application. It will also review how to put together a budget in a step by step manner as well as budget justifications. Reporting requirements and administrative information, qualifications, formatting requirements, National policy, and general information is shown here in the general application instructions.

What are milestones are, when everything is due is on the front page of the program announcement. So you can see when the pre-application submission deadline is all the way through the programmatic review, when that is going to happen.

Funding Opportunity Documents

Program Announcement

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs
Peer Reviewed Cancer Research Program
Virtual Cancer Center Director Award

Announcement Type: Initial
Funding Opportunity Number: W81XWH-20-PRCRP-VCCDA
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), July 30, 2020
- Application Submission Deadline: 11:59 p.m. ET, August 20, 2020
- End of Application Verification Period: 5:00 p.m. ET, August 27, 2020
- Peer Review: October 2020
- Programmatic Review, Stage 1: December 2020
- Invitation for Oral Presentation: December 2020
- Programmatic Review, Stage 2: February 2021

General Application Instructions

General Application Instructions
Version 501
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs

Table of Contents

I. HELPFUL INFORMATION 2

A. Tips for Success 2

B. Applicant Organizations 2

C. Current Funding Opportunities 2

D. Receiving Emails from CDMRP, eBRAP, and Grants.gov 3

E. Agency Contacts 3

II. eBRAP REGISTRATION AND PRE-APPLICATION SUBMISSION 4

A. Registration Requirements (All Applicants) 4

B. Content and Form of Pre-Application Submission 5

III. APPLICATION SUBMISSION FOR EXTRAMURAL ORGANIZATIONS 7

A. Grants.gov Application Package Components 11

B. Submission to Grants.gov 26

C. Applicant Verification of Grants.gov Submission in eBRAP 36

D. Application Tracking 27

IV. APPLICATION SUBMISSION FOR INTRAMURAL ORGANIZATIONS 27

A. eBRAP Application Package Components 27

APPENDIX 1 Regulatory Requirements 34

APPENDIX 2 Reporting Requirements and Administrative Information 42

APPENDIX 3 Qualification and Restrictions: Information 48

APPENDIX 4 Formatting Guidelines 49

APPENDIX 5 Selected Policy Requirements 50

Single most important tip:
Read both documents carefully

Submission Information

CDMRP utilizes a standard submission process

Step 1

Submit Pre-application in eBRAP

Preproposal

Letter of Intent

Receive Invitation to Submit Full Proposal Application

Step 2

Submit Full Application to Grants.gov (extramural) or eBRAP (intramural)

Step 3

Verify Application in eBRAP

All PAs use a two-step submission process:

(1) Pre-apps
(Preproposal or Letter of Intent) via eBRAP

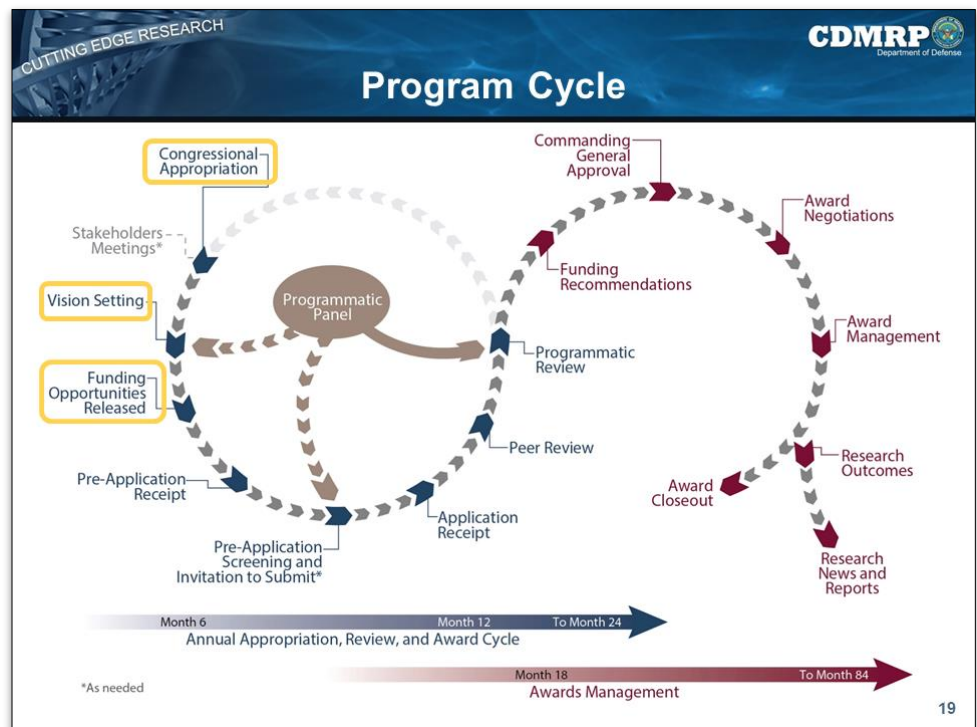
(2) Full apps
Grants.gov (extramural)

BO: Business Official from applicant organization eBRAP: electronic Biomedical Research Application Portal

Dr. Kimbark:

So if we go to the next slide, what's going to happen to your application and how do we get through this program cycle. First of all, let's look at that one box that says funding opportunities release. They were released at the end of March. We have for the pre-applications with the pre-proposals, those are due May 22nd. So you have until pre-application receipt to get something put together for the Ideal Award with special focus, for the Impact Award or for the Translational Team Science Award.

You have to put those together and pre-application screening will be reviewed by our Programmatic Panel and I'll talk to you a little bit about who they are. And then full applications will be invited and Peer and Programmatic Review will take place.



Now if you happen to be a young investigator and you're coming in as a early career investigator under a Career Development Award, you do not have to wait for an invitation. After you put in your letter of intent, you can just go right ahead and do the full application.

So let's go ahead and look at the submission information on the next slide. This is a step by step process. First, you have to do your first pre-application. The P.I. and the Business Officer should be working together to get this done. So your first step is a pre-application. It's either going to be a pre-proposal or a letter of intent. After that happens then you'll have to submit your full application to Grants.gov. The pre-application is submitted to eBRAP. The full application is submitted to Grants.gov. If you're extramural, if you're a DoD lab, you will submit it through eBRAP. Then you can do all of your verification of your application on eBRAP itself and I'll talk a little bit about that in a moment.

Let's go to the next slide and get in to what is the difference between a pre-proposal and a letter of intent. We call both of these pre-applications. You'll hear me talk about both of these. Both of them will be submitted through eBRAP.org and follow all the instructions. Now the pre-proposal, you have to prepare a one to two page narrative. That pre-proposal might also include submitting some biosketches and some other supporting documents. The pre-proposal will be reviewed by the Programmatic Panel. That Programmatic Panel then will submit a recommendation to invite you for a full application. You have to have an invitation to submit a full application for these types of award Mechanisms: The Ideal Award, The Translational Team Science Award, and the Impact Award.

Now the letter of intent is submitted through eBRAP as well. Follow all the instructions. The letter is just a statement of your intent to apply. It's always great to tell us what the title of your application might be, but it's not going to be reviewed by anyone. It's only used for administrative purposes. No invitation

is required to submit a full application. This is for the Horizon Award and the Career Development Award.

If we go to the next slide then, I'm going to tell you what happens to your application. After you put in your full application, you put in your pre-application. You're either invited or you don't have to be invited because you submitted a letter of intent. You submit your full application. After you submit your full application, what's going to happen is a review of your application. The review of your application is an evaluation by a two tier process. We have Peer Review and Programmatic review.

Peer Review is our criterion-based evaluation of the full proposal. Here we're determining the absolute scientific merit and what I mean by that is that the Peer Reviewers are instructed to review your application against the gold standard or a perfect application. They are instructed not to review or compare to other applications they have that are assigned to them. Therefore, they look at the criteria, they answer questions for that criteria, and give you the strengths and weaknesses and scores. The outcome is the summary statement that puts all of that together. There are no standing Peer Review Panels and there's no contact between reviewers and applicants.

Dr. Kimbark:

Now the summary statement which has those scores and strengths and weaknesses then goes forward to the Programmatic Review. Programmatic Review is important because here you're going to compare the proposals against one another. It's going to be determine about the adherence to the intent of the award mechanism and program relevance. This is what we're going to get as a funding recommendation. There's no pay line, okay? Funds are always obligated upfront. There's no continuation of funding.

So if we go to the next slide just to quickly go over a little bit more in depth the Peer Review. The Peer Review itself is a technical merit assessment and it's based on the ideal application, as I said. We're going to go over a little bit of that criteria-based evaluation of the entire application. The panels will be comprised of scientists, clinicians, active duty Service members as well as consumer reviewers. Consumer reviewers are lay people that have been affected by the disease. No standing panels, as I said, and reviewers are recruited based on their expertise needed. So that's why it's very important that you pick the right topic area and you make it very clear what your work is going to be about because I don't want you to be on the wrong Peer Review Panel. It's really important to do that.

So your outcome once again is summary statement. So let's look an example of Peer Review criteria.



When we look at an example of Peer Review criteria on the next slide you can see that this is the Peer Review criteria for scientific merit for the Ideal Award with Special Focus. So you can see there's a whole bunch of questions that the peer reviewers are going to evaluate. From how well the proposal research addresses an important scientific questions relevant to at least one of the FY19 PRC or Peer Topic Areas to what degree the statistical plan is appropriate for experimental methodology being used. Whether the applicant demonstrates the availability of tissue, data, or human subjects if applicable, and so on. So there's a bunch of different questions that the peer reviewers will be answering under each one of the topics of the peer review criteria.

This is just one peer review criteria; scientific merit. There'll also be innovation and impact and some other ones. So answer all the questions the peer reviewers evaluate. All of them are important for you to answer them.

They'll have your project narrative. And in your project narrative, what I've done, I take that project narrative and I marry it up with the scientific merit when I'm writing the program announcement. I ask questions on each one of the things in the project narrative. If you miss something, it's going to be very, very clear that you've missed it when we look at the scientific merit.


You go to the next slide, we'll talk about the next tier of review. That next tier of review is Programmatic Review. This is where they're doing that comparison based process. Here what they're doing is they take that summary statement and they look at how strong your scientific merit is, what the potential for impact is, what the program relevance is, how it connects up. And there is a consideration of portfolio balance and composition. That's especially important for Peer Review Cancer Research program because we have 15 topic areas and we do try to fund every single topic area. So that's really important.

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

First Tier: Peer Review

- ◆ **How the evaluation process works**
 - ❖ Technical merit assessment based on an ideal application
 - ❖ Criteria-based evaluation of entire application
- ◆ **Peer reviewers**
 - ❖ Panels comprised of scientific and consumer reviewers
 - ❖ No standing panels
 - ❖ Reviewers are recruited based on expertise needed
 - ❖ Identities are unknown to applicants; contact between applicants and reviewers are not permitted




**Outcome:
Summary
Statements**

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

Second Tier: Programmatic Review

- ◆ **How the evaluation process works**
 - ❖ Comparison-based
 - ❖ Strong scientific merit
 - ❖ Adherence to award mechanism's intent
 - ❖ Potential for impact
 - ❖ Program relevance
 - ❖ Consideration of portfolio composition
- ◆ **Programmatic reviewers**
 - ❖ Programmatic Panel members comprised of consumers, clinicians, and researchers
 - ❖ Ad hoc reviewers



**Outcome:
Funding
Recommendations**

The Programmatic Panel members are comprised of consumers, clinicians, researchers and active duty military. We also bring in Ad hoc reviewers because of the fact that we do have a number of different topic areas.

If we go to the next slide you'll see the names of some of the panel members. Our panel members, this is our panel that we have. This is not the Ad hocs. Ad hocs are added on an Ad hoc basis, obviously. You can see that Dan Dixon out of the University of Kansas is our Chair. We do also have Dr. Inman from Duke University Health, that's our expert in bladder cancer. Now I do want to point out that he's not the only Programmatic Reviewer that we will have for bladder cancer. We will end up with Ad hocs for bladder cancer as well.

Dr. Kimbark:

What I'm saying when I say do not include any of your Programmatic Panel members in your application, okay? None of these people that are on this slide can be on your application. Now, Ad hocs, I know you don't know who they are yet. I don't know who they are yet. We are still recruiting them. So Ad hocs, it's a given that you're not going to be able to cover those. Don't worry about those. These people that are on this slide, are the most important people that you must make sure that you do not include any Programmatic Panel members in your application. I can't emphasize that enough.

Pay attention to the details of the Programmatic Review criteria. Can you go back to the last slide please?

Pay attention to the details of the Programmatic review criteria because it's going to be important. Each one of them will change according to the different award mechanism. So it's important for you to pay attention to that.

And finally, don't phone it in for the military health focus areas. I don't know how many times I've seen people just phone that in and that's an important part of what the Peer Review Cancer Research program is. Our personality, our character, who we are as a program. You have to pay attention to the military health focus areas. So please take a look at what we have in our program announcements as well as on our website.

So go to the next slide. I'm just going to finish up with some strategies for success. Pay attention to what the program announcement says, especially in the program description and award intent. This will help you decide how to frame your project narrative. The impact is important as well. Clearly articulate why it's important. How does this work make a difference? We have clearly articulate translate ability. If

CUTTING EDGE RESEARCH
CDMRP
Department of Defense

Programmatic Panel

John Kuttesch, M.D., Ph.D. (FY20 Chair Elect) University of New Mexico	<p>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:</p> <ul style="list-style-type: none"> • Ratings and evaluations of the peer reviewers • Relevance to the mission of the DHP and FY20 PRCRP, as evidenced by the following: <ul style="list-style-type: none"> ◦ Adherence to the intent of the award mechanism ◦ Program portfolio balance and composition ◦ Relevance to the FY20 PRCRP Military Health Focus Areas ◦ Relative impact • Do NOT include ANY of the Programmatic Panel members in your application! • Pay attention to the details of the Programmatic Review Criteria! • Don't 'phone it in'!
Jonathan Brody, Ph.D. Thomas Jefferson University	
Clark Chen, M.D., Ph.D. University of Minnesota	
LCDR Alden Chiu Walter Reed National Military Medical Center	
Dan Dixon, Ph.D. University of Kansas Medical Center	
Paul Doetsch, Ph.D. NIH/NIEHS	
Lt Col Della Howell, M.D. Brooke Army Medical Center	
Brant Inman, M.D. Duke University	
Aaron Mansfield, M.D. The Mayo Clinic	
Robert Mesloh (Consumer) Lymphoma Research Foundation	
Lopa Mishra, M.D. University of Texas MD Anderson Cancer Center	
Col Thomas Newton Walter Reed National Military Medical Center	
Nancy Roach Fight Colorectal Cancer	
Kenneth Tanabe, M.D. Harvard University	

wanted to say that in plain language I would say speak clearly. Tell consumers and patient advocates why this is important. That's important that you write that in plain language with impact.

Identify the gaps that will be filled, especially in those innovative type award mechanisms.

The feasibility is really important. Always have answered the question of pitfalls. If there's other methods, alternative approaches that you might want to do. Make sure that you justify how you're going to do this and what you're going to do if something fails.

Don't have interrelated aims. They should be clear and concise aims. They should have an overarching goal but you shouldn't have one aim that is very, very dependent on another. If it's very dependent on another, that means that they are one aim that should have a sub-bullet, so don't do that.

Ensure that study is appropriately powered and demonstrate availability and access to your critical resources.

Going to the next slide. Pay attention to your timelines. When I say that something is due, the application for submission deadline for the Career Development Award is September 18th, don't come to me on September 19th and beg me to let you in. I'm not going to let you in. It's not going to happen.

We do allow for a verification period. That verification period will allow you to take a look at your application after the September 18th deadline, but it takes about 72 hours for Grants.gov to download everything so you can see it. So you should start early. You should put it in early. You shouldn't be submitting on September 18th. Everything should be submitted before then so you can see what the issues are early on.

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

Strategies for Success

- ✓ **Relevance**
 - ❖ Address program-specific goals
 - ❖ Align the proposed work with specific guidance from the announcement
- ✓ **Impact**
 - ❖ Propose solutions to important problems
 - ❖ Clearly articulate translatability – how will this work make a difference?
- ✓ **Innovation**
 - ❖ Identify gap(s) that will be filled and novel approaches used
- ✓ **Feasibility**
 - ❖ Justify a technically sound plan with clear approaches for contingencies
 - ❖ Include evidence of appropriate **EXPERTISE** (collaboration, consultants, etc.)
 - ❖ Ensure the study is **APPROPRIATELY POWERED** for the proposed research outcome
 - ❖ Demonstrate **AVAILABILITY** and **ACCESS** to critical resources, reagents, and/or subject populations

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

Strategies for Success

- ✓ **Planning/Timelines**
 - ❖ Include and allow adequate time in project plan for regulatory approvals if required
 - ❖ For multi-organizational efforts, show a clear plan for **COORDINATION** and communication
 - ❖ For DoD collaborations, understand rules and plan for differences in funding process
- ✓ **Grantsmanship**
 - ❖ Explain the proposed work with **CLARITY** and **UNBURDENED** by jargon
 - ❖ Understand the different audiences of the peer and programmatic reviews and **COMMUNICATE** effectively
 - ❖ **REVIEW** application documents carefully before submission – Enlist experienced colleagues to help
 - ❖ Don't break the rules for deadlines or requirements – **BE COMPLIANT**



Dr. Kimbark:

That's Grantsmanship. Grantsmanship is being clear, unburdened by jargon. You don't want to have a sentence that has so many acronyms or so many abbreviations that it's going to tire the Peer Reviewer out. You want the Peer Reviewer to be saying this was an eloquently written application that was easy to understand and follow. That's what you want. And once again, be compliant with the deadlines.

Some strategies to avoid pitfalls. Like I said, do not include any Programmatic Panel members for the program and fiscal year to which you are applying. Don't exceed the page limits. You might think that you didn't exceed the page limits, but when you converted to PDF suddenly you have a couple of lines over. Don't do that. I can't do anything about it. You end up with a bad one and we have to make you non-compliant. I hate making people non-compliant for that. Do not miss the submission deadline. The Grants.gov validation may take up to 72 hours. Application verification in eBRAP is possible before the deadline. You have to submit the correct narrative and budget because these cannot be modified during the verification period.


We go to the next slide. These are some websites that you might want to look at. Our CDMRP website with our PRCRP. You'll find more information on military health focus areas. There's also a video on our CDMRP that gives you an overview of CDMRP if you are interested

in that. We also have a webinar series. It's really more of a video series that goes into more detail on the funding opportunities, how to get through the funding opportunities and go through in detail all of that. How to answer high risk high gain type of award mechanisms or what a team science award mechanism

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

Pitfalls to Avoid in Application Submission



- ◆ Do not include Programmatic Panel members for the program and fiscal year to which you are applying
- ◆ Do not exceed the page limits; check files after creating PDF version
- ◆ Do not miss the submission deadline
 - ❖ Grants.gov validation may take up to 72 hours
 - ❖ System-to-system submissions are sometimes problematic
 - ❖ Application verification in eBRAP is possible before the deadline
- ◆ Submit the correct Project Narrative and Budget
 - ❖ These components cannot be modified during the verification period in eBRAP

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

FY20 PRCRP Timeline

◆ Pre-proposal Mechanisms Deadlines	◆ Letter of Intent Mechanisms Deadlines
◆ Pre-Application Submission Deadline: 5 pm ET, 14 May 2020	◆ Pre-Application Submission Deadline: 5 pm ET, 30 July 2020
◆ Invitation to Submit an Application: 16 June 2020	◆ Application Submission Deadline: 11:59 pm ET, 27 August 2020
◆ Application Submission Deadline: 11:59 pm ET, 27 August 2020	◆ End of Application Verification Period: 5 pm ET, 3 September 2020
◆ End of Application Verification Period: 5 pm ET, 3 September 2020	◆ Peer Review: October/November 2020
◆ Peer Review: November 2020	◆ Programmatic Review: December 2020/February 2021
◆ Programmatic Review: February 2021	
◆ <u>Pre-application refers to the preproposal 1-3 pages.</u>	◆ <u>Pre-application refers Letter of Intent which is a letter stating you intend to apply. It is NOT reviewed!</u>
◆ <u>The pre-proposal is reviewed!</u>	◆ <u>This is for all other funding opportunities TTSA, CDA, BHSA, VCCDA!</u>
◆ <u>This is for Idea and Impact Award funding opportunities only!</u>	◆ <u>You DO NOT need an invitation to submit!</u>
◆ <u>You need an invitation to submit!</u>	

29

would be like and how to go through all of the program announcements in that way. So there's a lot of good types out there that are available for you to take a look at.

CUTTING EDGE RESEARCH

CDMRP
Department of Defense

For more information, please visit:

cdmrp.army.mil/prcrp

https://cdmrp.army.mil/pubs/video/CDMRP_overview

https://cdmrp.army.mil/pubs/Webinars/webinar_series



30

Stephanie Chisolm:

Thank you so much, Dr. Kimbark. This was very informative and remember that we will posting the recording and we will be sending it out. There are some questions from participants in the live program. The first question is, **for the Career Development Award, my publication history is on prostate cancer. Do I need to establish a publication record in bladder cancer prior to applying?**

Dr. Kimbark:

No. You do not. I would suggest that you make sure that there is an expert on your team in bladder cancer and you make it very clear that they're going to be part of the process so that it's shown that you do have the support of bladder cancer experts. That would be the best way to go with that one. You do not have to show particularly that you have publication in bladder cancer for the Career Development Award.

Stephanie Chisolm:

The next question is **if I am a Research Assistant Professor do I only qualify for the Career Development Award or am I considered an Assistant Professor by the CDMRP?**

Dr. Kimbark:

As a Research Assistant Professor, it depends really... This is where it gets a little bit foggy. What I can tell you is that you probably would not be considered eligible for things like the Impact Award. The Impact Award is really the Assistant Professor and we consider those two different types because a Research Assistant Professor is usually not tenure track. The Research Assistant Professor should really go into the Career Development Award mechanism or possibly the Idea Award Mechanism. That would be a good place to be. Or you could possibly as a partner for the Translational Team Science Award.

Stephanie Chisolm:

When is the pre-application due for the Impact Award and Translational Award? Can you just remind us about that?

Dr. Kimbark:

The Translational Team Science Award, the Impact Award, and the Idea Award with Special Focus, the pre-proposal is due on May 22nd at 5P.M. Eastern time. Okay?

For the letter of intent for the Horizon Award or the Career Development Award, those are due on August 28th at 5PM. I can also tell you that all of them, the full application is due on September 18th at 11:59P.M. in Grants.gov.

Stephanie Chisolm:

Great. Thank you so much. **For the Career Development Award, what is the required percent of effort. I guess from the P.I.?**

Dr. Kimbark:

The required percent of effort is a little bit different this year then we've had in the past. One of the things we want is that the P.I.'s organization must demonstrate a commitment to the P.I. through confirmation of laboratory space and at least 50% protected time for cancer research.

It's cancer research. It's not specifically for this award mechanism. You have to be doing at least research in cancer 50% of the time, but it doesn't have to be 50% on this award.

Stephanie Chisolm:

Great. **There's an investigator who is 9.5 years from their PhD, but they also spent two years within that timeframe within that time frame getting a Masters in Clinical Investigation. Would that put that person at 7.5 years for the Career Development Award or does the entire period of time count as time from that terminal degree?**

Dr. Kimbark:

The terminal degree probably is the higher degree. That's usually the PhD, so I would go with the PhD or the Medical Doctorate, whichever one it was.

Stephanie Chisolm:

So you wouldn't be able to put a pause button on for those additional two years for that Masters in Clinical Investigation?

Dr. Kimbark:

Probably not. We really do try to do our best with that. If there is a lot of questions about it, usually we actually end up falling on the side of being conservative. And conservative is on the side of the applicant, but I don't want you to feel like I'm giving you a yes you can apply and then suddenly our Grants Officer who is with our decision authority says no.

I want to give you the answer that would be the best for you at this point. I would be a little bit iffy on that one.

Stephanie Chisolm:

Okay. **One of our participants asked if I received a 2.1 for an IDA Award this year, should I consider submitting a similar grant this year and what should I keep in mind for the resubmission. Any tips for improvement?**

Dr. Kimbark:

We don't really accept resubmissions, but you can submit again, okay? Say you want to submit with the same idea, which is fine. What you have is a little piece of gold in your hands and that is the summary statement. That summary statement, what you're going to do is you're going to go through and you're going to look at the strengths, make sure you that you repeat those. Then you're going to look at the weaknesses You're going to make sure that you answer those within those strengths. And make sure that you don't hand wave any of your answers. Like I said, don't phone in the military health statements. That is really an important part of what you have to put together.

Pay attention. Bladder cancer gets a really good receipt so if you're in competition with your other bladder cancer people, then you really have to make a really strong case. So your summary statement with those weaknesses are telling you where you kind of fell off track, got a little bit behind everyone else. So use those weaknesses and answer those weaknesses and hopefully you can increase your score.

Stephanie Chisolm:

For Career Development Award, there's the designation of an independent investigator. If you are a clinician and do not have a lab, could you still be considered for independent designation if you have a lab mentor?

Dr. Kimbark:

If you have a space in someone's laboratory, we actually say laboratory space instead of independent laboratory in the actual write up in the program announcement. If you have laboratory space in your career guides laboratory for instance and that's where you're going to be doing your lab work, sure you can go ahead and apply.

Stephanie Chisolm:

Regarding the CDA for clinical and translational investigators with a medical background, does the 10 years count from the completion of the MD or the completion of clinical fellowship which would be regarded as the end of training?

Dr. Kimbark:

The actual information actually says that the 10 years after completion of his or hers terminal degree by the time of the application deadline, excluding time spent in residency, clinical training, or on family medical leave.

Stephanie Chisolm:

If I am a VA employee/Researcher with a career development award or merit, do I qualify to apply to CDMRP?

Dr. Kimbark:

Yes.

Stephanie Chisolm:

How many Impact Awards are expected to be given this year for bladder cancer? Last year we got 1.3 in the Impact Award, but I heard there was only one award which was given in the last year in that area.

Dr. Kimbark:

Well I can't tell you how many are going to be given in bladder cancer. That's not something that we set our investment strategy for. That's now how we work it. We actually have an overall amount that we're planning on giving for bladder cancer and I believe that we're planning on giving 10, I think, for overall. For all of the different Impact Awards that we will give. Now whether or not we give one for bladder cancer or not still remains to be seen.