

The Congressionally Directed Medical Research Programs

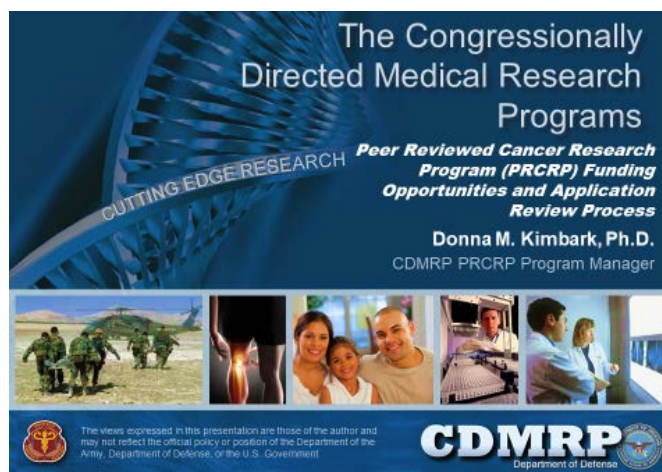
Peer Reviewed Cancer Research Program (PRCRP)

Funding Opportunities & Application Review Process



2018 Webinar presented by Donna Kimbark, PhD, program manager for the Peer Reviewed Cancer Research Program at the CDMRP.

Dr. Kimbark: Thank you very much. I'm excited to discuss the Peer Reviewed Cancer Research Program today, the opportunities and application review process. I want to make a point that I'm going to talk a little bit about who CDMRP is, as well as talk to you in-depth about the Peer Reviewed Cancer Research Program, and then give you some tips for success in what we generally call grantsmanship.



What is CDMRP? Let's talk a little bit about what the Congressionally Directed Medical Research Programs, who they are and where they sit, so that you can get a foundation of what you're going to be led to expect. The CDMRP is part of the Department of Defense. We are part of the Department of the Army specifically. We are part of the Medical Research and Materiel Command. We actually sit up at Fort Detrick in Maryland.

The hallmarks of the CDMRP, I'm going to go in-depth in a moment, but let's talk a little bit about the vision and mission of the CDMRP, which is very

important to understand when you're trying to answer some of our applications and solicitations. Our vision is really about transforming healthcare for service members and the American public through innovative and impactful research. You're going to hear those words, innovation and impact, more than once throughout this talk today, because the CMRP is really about funding those groundbreaking, high impact research proposals that are going to change the face of what we know as healthcare today. How we do that is by managing collaborative research that discovers,



develops, and delivers healthcare solutions for service members, veterans, and the American public overall.

A presentation slide titled "Hallmarks" for the CDMRP (Congressional Defense Medical Research Program). The slide features a blue header with "CUTTING EDGE RESEARCH" on the left and the "CDMRP" logo on the right. The main content is a list of hallmarks, flanked by two columns of three small photographs each. The photographs show diverse groups of people, including families, military personnel, and researchers. The hallmarks are listed in a central column with bullet points.

Hallmarks

- Targeted research funds are added to the DoD budget by Congress
- Funds high-impact innovative research
- Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- Follows the National Academy of Medicine-recommended model for application review
- Consumers participate throughout the process
- Annually adapts each program's vision and investment strategy allowing rapid response to changing needs
- Funding flexibility
 - Funds obligated up-front; limited out-year budget commitments
 - No continuation funding
 - No "pay line"; funding recommendations are based on portfolio composition, adherence to intent of mechanism, and relative impact, in addition to technical merit

As I said, the hallmarks of the CDMRP are important to understand, the character of the programs, as well as understand how you should answer some of these applications. The first and foremost thing is that most of the CDMRP funds are targeted funds that are added to the DoD appropriation by Congress. In fact, we are not in the president's budget. I think that's one of the most important things that you can get out of this, as who CDMRP is. We are not in the president's budget. In fact,

stakeholders, advocates, and people that have the disease, we often call them consumers, and other people, other concerned researchers, and people in the field go to the Hill each year asking for Congress to add these funds to the DoD appropriation. Once they're added to the DoD appropriation, then our programmatic cycle moves forward. I'm going to talk to you in-depth about that.

The funds are about high impact, innovative research. I think very often we talk about impact and innovation, but we never really think about what that means. In fact, it means an awful lot to who CDMRP is. We really like to characterize ourselves as innovative. How we do that I'm going to discuss throughout the slides today. We do try to avoid duplication with other federal funding agencies, as well as non-federal agencies. That's important, because why would you want to do something duplicative over, and over, and over again? Yes. You want to repeat an experiment, but you don't want to keep on just funneling the money into that area.

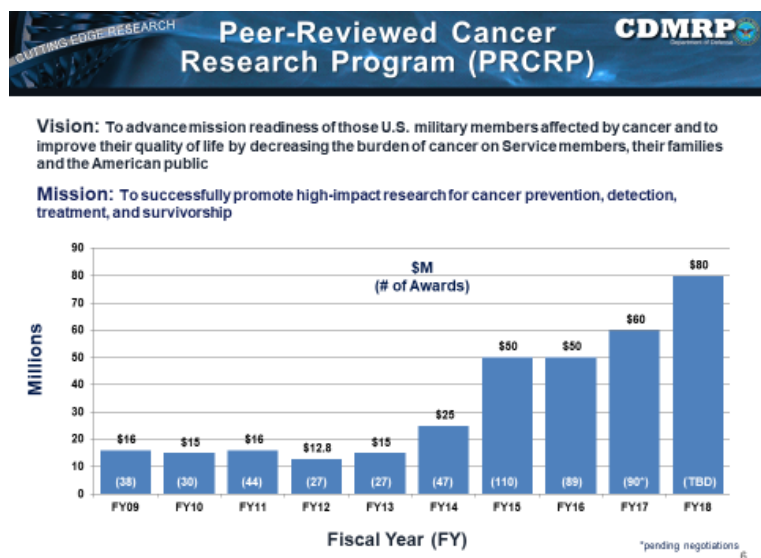
What you really need to do, is you need to look at a broad scope of what the research landscape is, as well as the funding landscape, and take a look at where are the unmet gaps? Where are the unfunded areas or the underfunded areas? Those are areas that the CDMRP tries to identify and tries to go towards, because we are complementary to other funding organizations. We are not in competition. We are complementary.

How do we fund our applications? That all goes back to the early 1990s, when the CDMRP first came about, we went to the Institute of Medicine, now called the National Academy of Medicine, and asked, "How should we solicit for applications, and how should we review these applications once we solicit them?" They gave us a recommendation to use a two-tiered review system that I'm going to go through in-depth for you, so that you understand the CDMRP model of application review. That's one step towards having good grantsmanship.

As I said, consumers participate throughout the process. That's really an important hallmark of who CDMRP is. The reason being is that consumers are people that have the disease, bladder cancer for

instance, or they're people that are caretakers of people with the disease, so that's an important process, that they continue to be part of who CDMRP is. It gives us a sense of urgency and importance in that area.

Additionally, it is important to note that each program that we have has its own vision and investment strategy, and we can change this on a yearly basis. Because of the fact that we're not in the president's budget, we never know if we're going to exist in the coming year. If we don't know if we're going to exist in the coming year, we really need to answer that impact question. What is the impact of this program? We need to answer that today, not in 10 years, not in 20 years, and so on. We need to answer it today, because we don't know whether or not we're going around tomorrow.



The Peer Reviewed Cancer Research Program has been around, surprisingly, since 2009. We really didn't know we were going to be around. I remember when we had that first meeting, we talked about only being around one year and what we could be, what we could be for that one year. That first year we had a \$16 million appropriation, but since then, for the last 10 years, we've been growing. You can see, the first couple of years we stayed in the teens, but we popped up to 25 million, and now for fiscal year 18 we are at \$80 million at this point.

So, we have a good chunk of change to invest in our cancer topic areas.

It is important to note what our vision is and why we are here. We're really about advancing mission readiness to military members that are affected by cancer, as well as improving the quality of life by those that have the burden of cancer on their shoulders, both service members, their families, and the American public. We do this by promoting high impact research for cancer prevention, detection, treatment, and survivorship. So, these are the specific vision and mission statements for the Peer Reviewed Cancer Research Program that's under the umbrella of the Congressionally Directed Medical Research Program.

Each year, each one of those years that I showed you, from fiscal year '09 through fiscal year '18, we have congressional language. We actually get a paragraph in the DoD appropriation, not just a line item. We get a paragraph telling us what our topic areas are and some other caveats about how the Peer Reviewed Cancer Research Program should be managed. For a fiscal year '18 you can see all of our topic areas that are listed

Strategic Guidance

CDMRP

Congressional Language: FY18 Topic Areas

FY18 Topic Areas

- Adrenal cancer
- Bladder cancer
- Blood cancer
- Brain cancer
- Cancer in children, adolescents and young adults
- Colorectal cancer
- Immunotherapy
- Listeria regimens for cancer
- Liver cancer
- Lymphoma
- Melanoma and other skin cancers
- Mesothelioma
- Myeloma
- Neuroblastoma
- Pancreatic cancer
- Pediatric brain tumors
- Stomach cancer

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

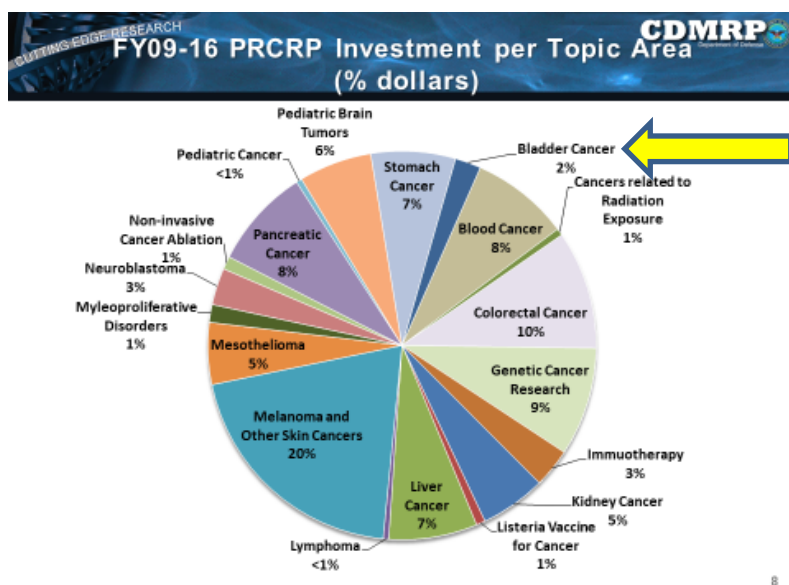
Funds may not be used for research into breast, prostate, ovarian, kidney or lung cancers

Research progress should be relevant to Service members and their families

there. There are 17 topic areas. We do have the new topic area of adrenal cancer. Blood cancer came back this year. It wasn't with us for a couple of years, but it's now back, and we also have myeloma, which is a type of blood cancer, but it's been called out as a specific topic area as well. Bladder cancer is with us this year as well.

Some other things that are important to note for our congressional language is that *applicants must address at least one of these topic areas*, as directed by Congress. You can't just decide, "Oh. I don't like any of these topic areas. I'm going to pick my own." You have to pick one of these, but since this is a community for bladder cancer, I'm assuming you're probably all going to pick bladder cancer, so we're good to go there. The funds may not be used for research into breast, prostate, ovarian, kidney, or lung cancers. That's important, because of the fact that those cancers already have their own programs that are managed and executed by the CDMRP, so we're not going to put our funds into that, and Congress says we can't anyway, which is good.

Finally, our research program should be relevant to service members and their families. Now, a lot of people say, "*How do you make cancer relevant to the military? How do you make it a military focus?*" I'm going to walk you through how to do that in detail to make things easier for you when you do have to answer that requirement. We'll be doing that in just a little bit.



Our investment per topic area is shown here. You can see that bladder cancer is up near the top there. It's about 2%. You say, "That's not a lot. Look at melanoma and other skin cancers. They're like 20% already." You also notice down near around 5:00, 5:30, you'll see kidney cancer there. Kidney cancer used to be part of the Peer Reviewed Cancer Research Program, but it has been pulled out as its own separate program now. But let's address why melanoma and other skin cancers has 20% and bladder cancer only has 2%. How is that fair?

We have a balanced portfolio here. Look at the years up there at the top. At fiscal year '09 through fiscal year 2016 for the Peer Reviewed Cancer Research Program the only topic area that was mandated by Congress to be within the Peer Reviewed Cancer Program all the way through, from '09 through actually '18, is melanoma and other skin cancers. I want to tell you right now, I do not sit at my desk and throw darts at a board to decide which cancers are going to be added. Like I said, this is congressionally directed, so Congress answers the needs of their constituents. If the constituents, the stakeholders, the consumers, the advocates, the concerned researchers go to Congress and ask for a cancer to be added, it is then added.

Bladder cancer was added in fiscal year '16 for the *first time*, so you can see that there's 2%, as opposed to 20%, because melanoma and other skin cancers has been with us since the get-go, so there is a

difference there. It is a changing pie at all times, but you can imagine that this pie might be manipulated by many different factors, not only whether or not the topic area is actually there. A topic area, for instance, colorectal cancer has been with us since 2010, and it has about 10% of the funds added to it. That is, there is a number of different reasons for that.

There are a number of different reasons that pancreatic cancer's at 8%, mesotheliomas at five. That's because of the fact not only about whether or not the topic area is in the language, but the number of applications we get. That's really important, the number of applications. I'm going to show you how this affects things, especially for bladder cancer, in just a bit, not only the number, but also how meritorious, as far as scientifically meritorious and impactful those applications are. So, those are important aspects that will influence how this portfolio pie will end up looking.

PRCRP Congressional Language

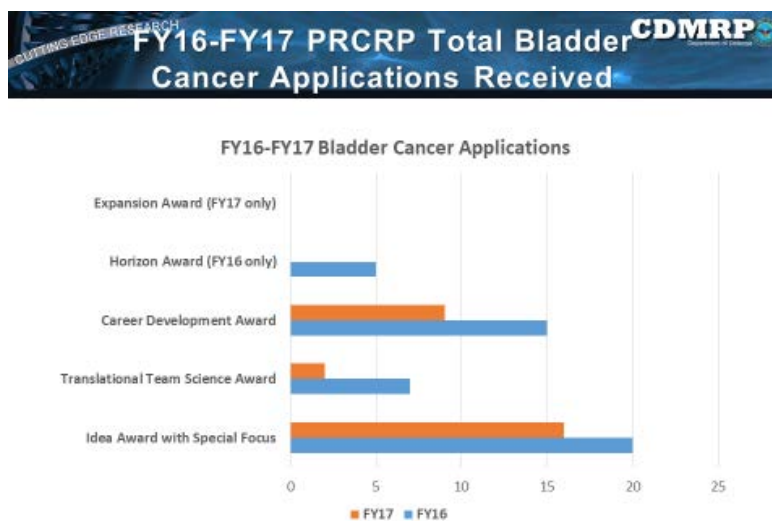
- Congressional language stipulates the Topic Areas to be funded, the appropriation amount, and the requirement that research is relevant to Service members and their families
- Over the ten years of the PRCRP, 23 Topic Areas have been included in the Congressional Language. The Fiscal Years (FY) Bladder Cancer have been included are shown below:

Topic Area (FY appropriation):	FY09-15 (PRCRP: \$149.8M)	FY16 (PRCRP: \$50M)	FY17 (PRCRP: \$60M)	FY18 (PRCRP: \$80M)*
Bladder Cancer		✓	✓	✓

You can see that bladder cancer started in 2016 in PRCRP. It's been with us in 2017, as well as 2018. We're excited to see it continue in our pie. When we look at 2016 and 2017, so far 2016 and 2017, those cycles are complete. 2016, those awards are running. People are doing their research. 2017, we're right at the point of negotiating them, and people are getting their money. But let's look at

these two different years and see the difference. For 2016, it was the very first year. There was a lot of excitement. I did a couple of webinars. I think I did one for the American Urological Association.

You can see that for 2016, which is that blue bar, you can see the number of applications that we got for bladder cancer applications. Last year, for FY17, you can see the number of applications we got for bladder cancer was substantially lower. Was it because of the type of award mechanism we offered, or was it because of everybody was fat and happy from the year before? I hope not. Or was it because of the fact that maybe I didn't give a webinar for bladder cancer? I'm not sure. Maybe we didn't get the word out well enough to the research community. I'm not sure, but it's important to keep in mind that being alert to when the PRCRP is offering program announcements or solicitations to pull in those applications, it's important to apply, so that we can in fact fund bladder cancer applications.

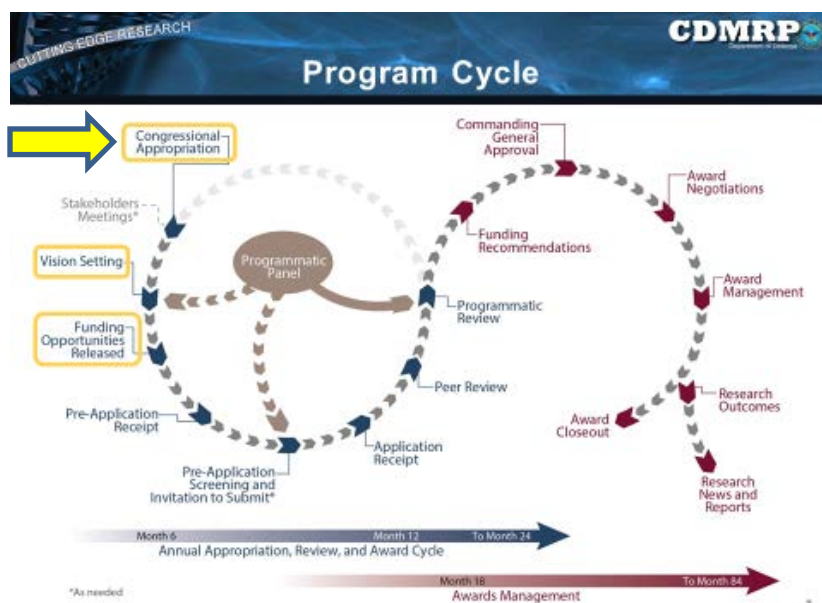


Right now I'm just going to go into a list. I'm not going to go into depth into any of these right now. You can pull all of this information down from our website, and you can see the recommended budgets that

we had from the different applications that we got. If you look at the log number, if there's a 16 right after the CA, which was from fiscal year '16. You can see for FY16 the bladder cancer awards were about five and a half million dollars we invested in bladder cancer. For FY17, because of a decrease in applications, there was of course a decrease in the number of bladder cancer awards and investments that we made. It's about, excuse me, 2.8 million in bladder cancer investment.

Hopefully this year we can really pick that up and **get more robust application receipts and therefore more in the area of bladder cancer.**

Now I'm going to go into a little bit about our program cycle, so that you can understand how applications get reviewed, and after that, how applications get reviewed, I'm going to talk to you a little bit about what those funding opportunities are, how to find them, as well as some tips for success. The programmatic cycle starts with the congressional appropriation. You can see that that's about at 10:30 on that first circle with the big ... It says congressional appropriation at that arrow. Stakeholders meetings do happen in the inaugural year of a program. PRCRP's stakeholder meeting was in 2009, so we haven't had one since then, since we've been around.



Then after the congressional appropriation comes in, remember, for fiscal year '18 the appropriation for PRCRP is \$80 million, the first thing that we do is we have our vision setting. Our vision setting is done by a panel of experts called our Programmatic Panel. Our Programmatic Panel includes people from the clinic, includes people from the lab, as well as consumers and active duty oncologists. All together, they sit down, and they look at that funding landscape, and that

research landscape, and what's needed for patient care. When they look at all of this, then they come up with an investment strategy.

The product of that investment strategy happens to be the program announcements, or funding opportunities, or you may hear me call them solicitations. Those solicitations are then released, and we get in pre-applications. Those pre-applications, there's some mechanisms where a pre-application, a write up, and a pre-application that is a one to three page pre-application is brought in. The Programmatic Panel then reviews them, and then you will get an invitation to submit a full application.

Some funding solicitations do not require a pre-application. All they require you to do in that first step is to send in what we call a letter of intent... You can write in, "I'm planning on submitting a full application," and that's a letter of intent. So, there is a difference there, and I will explain to you which funding opportunities that the PRCRP offers, which ones will require your pre-application.

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

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The application receipt then occurs after the invitations are submitted, and then we have peer review and programmatic review. Peer review and programmatic review are our two-tiered review system that the Institute of Medicine or National Academy of Medicine, as it is known now, first recommended to us. I'm going to go into detail how that works in a moment. After the review process, we get our funding recommendations. The commanding general will approve them, and then finally we will do award negotiations and award management. We monitor the awards throughout their lifetime.

Now, let's get into that two-tiered review process. It's really an important part of the process, because once you understand the two-tiered review process, I think things start falling into place. There's the peer review and the programmatic review. As you saw from the last slide, the programmatic review is really done by the Programmatic Panel, but I want to tell you how these two separate entities work in conjunction, but also separately. I think that's really important to note.

Goal of the Two-Tier Review Process

To develop funding recommendations that balance the most meritorious science across many disciplines and offer the highest promise to fulfill the programmatic goals set forth in the relevant Program Announcement



What is peer review? Many people that are in the science community realize what peer review is, and they might even be part of a study section and so on, and they believe that peer review is pretty much standard. I mean, yes, you're evaluating a full proposal. Okay? But how does peer review and programmatic review differ? Let's go and talk a little bit about peer review first. For us, peer review is really about looking at that application on its own merit against the criteria that is written in the program announcement. That criteria is usually near the back of the program announcement.

When you look through that, when the reviewers are looking through your application, they're scoring. They're scoring numerically. They're scoring with strengths and weaknesses, detailing all your [application] strengths and weaknesses. *Are they comparing them against one another?* No. We tell them specifically, "Do not compare the applications against one another." What we want those to compare them to, is the ultimate gold standard, the ideal application. They want to compare them against the ideal application.

Therefore, peer reviewers do that, and then we get what we call summary statements, a little bit about the peer reviewers themselves. We have scientists, and clinicians, and depending on the award mechanism, it might be tech transfer specialists, or bio statisticians. We always have consumer reviewers on the panel that have full voting rights on the panel. The consumers are recruited based on their expertise, and they're recruited on a yearly basis. We do not have standing panels, and the identities between the applicants and the peer reviewers is not noted until after the awards are made. We do have that outcome of the summary statements, which contains the numeric score, as well as the strengths and weaknesses.

That all goes forward to **programmatic review**. At programmatic review, this is where our Programmatic Panel comes together. Now, remember, those are clinicians, laboratory scientists, active duty oncologists, as well as consumers, all sitting around and looking at what the summary statement says. It's really important, because at this point what they're going to do is begin looking at the intent of the award mechanism, which is written in the program announcement for all applicants to read, the intent of the award mechanism.

They want to see how well you adhered to the award mechanism. They want to look for the potential for impact. They want to look for program relevance, as well as they want to consider portfolio composition. That's really important as well.

Our Programmatic Panel has been really cognizant of making sure that each and every topic area is funded. There's only been one topic area throughout the many years, the 10 years that Peer Reviewed Cancer Research Program has been around that has not been funded. That was radiation protection utilizing nanotechnology. No meritorious applications were received, therefore it was not funded, but every single other topic area has been funded.

Programmatic panel members, we do have ad hoc reviewers added onto our panel. Now, you can imagine with topic areas that change on a yearly basis, because they do, sometimes we have a topic area. Sometimes we don't. Sometimes it comes back. Sometimes we get new topic areas all of a sudden. Now, with all of that flux, you can imagine that having a Programmatic Panel members have that expertise might be somewhat problematic. What we do now is we bring in ad hoc reviewers, to ensure that we have the correct expertise on the panel to do a fair review and give us a fair funding recommendation.

How do you go about actually doing the application and applying?

Let's talk a little bit about where to find those funding opportunities. This is probably one of the most important slides that I'm going to talk about today, because right in the center is the [URL](#). I would suggest you write that down if you have the chance to. Now, if you don't have anything to write it down



CDMRP
Cancer Discovery Mechanism Research Program

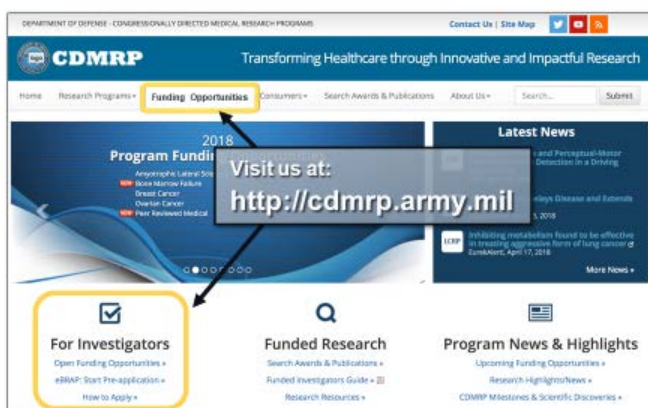
Second Tier: Programmatic Review

- **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

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Funding Opportunities on the CDMRP Website

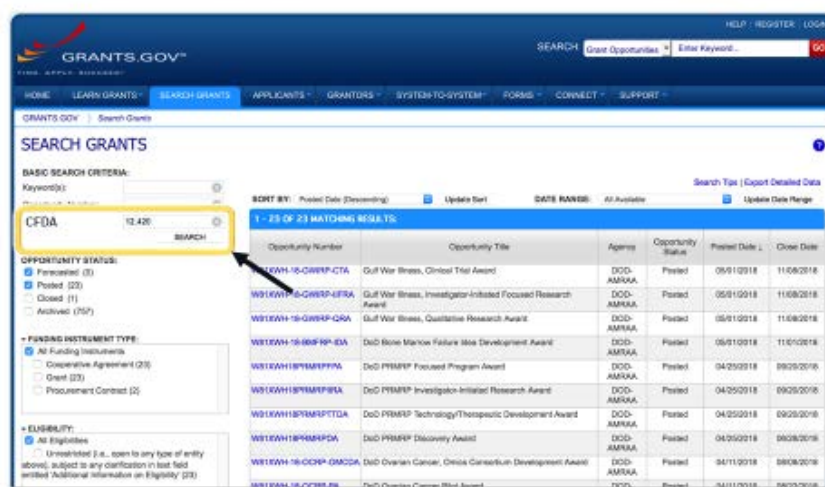


with, all you have to do is go to your favorite search engine and write in the letters C-D-M-R-P, and it will pop right up.

What you're seeing there is something that's really important, is where to find those funding opportunities. That's where you click in order to go to our portal, in order to find your way towards starting an application, that first step of the process. Everyone has to do the first step of the process through that portal, so really click there. That's really an important place to start.

Some people will be on grants.gov, for instance. You'll say, "Oh. I'm on grants.gov. I didn't go to the CDMRP website, because I couldn't remember the acronym. I kept on putting in CDMRP or something like that." Okay. You go to grants.gov, and you're trying to find the PRCRP funding opportunities. You see where that CFDA number is? You can put in 12.420, and all of the funding opportunities for the CDMRP will pop up. You will scroll down, and you will find the PRCRP one.

Funding Opportunities on Grants.gov



Which PRCRP ones do we have out this year? These are the ones that we have. These are synopses, very quick snapshots of each one of these, so you really need to go into the program announcements and look at it in more in-depth. The Idea Award With Special Focus, the Impact Award, the Translational Team Science Award, those three are slightly different than the Career Development Award. So, I'm gonna talk about the first three. Then I will talk about the Career Development Award. The Impact Award is for an assistant professor or higher. This is really supporting those projects or ideas that are specifically focused on critical scientific and clinic cancer issues. We're really looking to push forward and make a huge impact, a really large impact on one of those topic areas. While preliminary data is required, we are not looking for your recycled RO1 application. What we're really looking for is the intent is to really show applicability and translatability. We want it to go towards the next step towards clinical care. The direct costs are a million dollars over three years.

CUTTING EDGE RESEARCH

FY18 PRCRP Funding Opportunities

CDMRP
Department of Defense

Idea Award with Special Focus	Impact Award	Translational Team Science Award	Career Development Award
<ul style="list-style-type: none"> • All researchers with faculty level appointment eligible • Supports innovative, high-risk/high gain research • Emphasis on innovation • <u>Special Focus on military relevance</u> • Preliminary data discouraged • Direct costs - \$400k over 2 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, which, if successfully addressed, have the potential to make a major impact on one of the FY18 PRCRP Topic Areas. • <u>Emphasis on military relevance</u> • Preliminary data required • Direct costs - \$1M over 3 yrs. 	<ul style="list-style-type: none"> • Assistant Professor or above eligible • 2-3 PIs partner • Supports correlative studies associated with an ongoing, completed trial • Clinical Trial support • <u>Emphasis on military relevance</u> • Preliminary data required • Direct costs - \$1M amongst the partners over 4 yrs. 	<ul style="list-style-type: none"> • Independent investigator within 10 years of terminal degree • Career Guide at level of Associate professor • Supports impactful research • <u>Focus on military relevance</u> • Preliminary data not required • Direct costs - \$360k over 3 yrs.

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The last one that needs an invitation to submit is the Translational Team Science Award. That's an assistant professor are eligible. What you're going to have is a number of PIs collaborating together on a synergistic, hypothesis driven, correlative study associated with an ongoing or completed clinical trial. The clinical trial

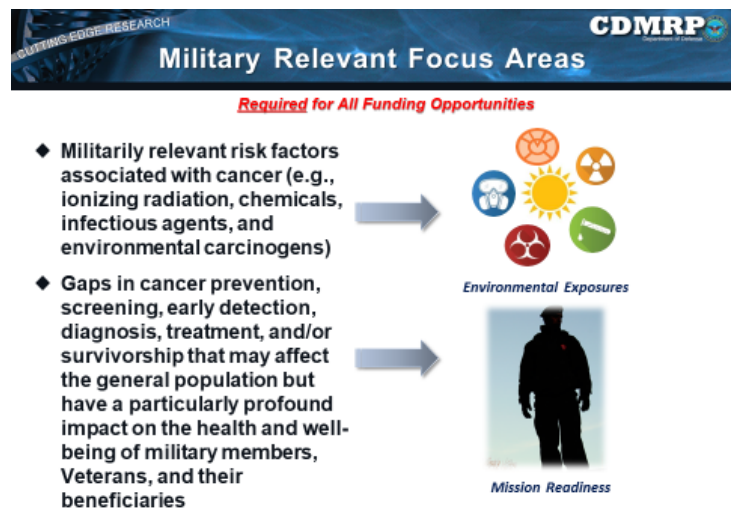
support is allowed within the budget. What you're really looking for is to put all these people together to work on an overarching issue or problem in one of the topic areas. Once again, we have the emphasis on military relevance. Preliminary data is of course required. We have \$1 million amongst the partners over four years.

Those three require an invitation. The Career Development Award does not require an invitation. All you have to do is your first step in order to apply is to put in a letter of intent. After that letter of intent, which is due on August 28th, after you put in that letter of intent, you have just a couple of weeks in order to finish up your application. September 12th for that application. For the other three, the application is due on September 26th. When you look at the Career Development Award, the eligibility is independent investigator within 10 years of terminal degree.

We understand that some people will have been in residency, so residency does not count against that 10 years, so the clock does not click during the residency period. It does not tick if you left work for family medical leave. For instance, you may have stayed at home in order to take care of a child or elder care, for instance. That does not count against you. Just make it clear in your bio sketch what you were doing during that time period. Post-Doctoral Fellows are not eligible to apply for this award mechanism. A career guide in an associate professor level is needed. This career guide is really mentoring people throughout the associate wickets of career. Really, we're supporting impactful research here.

The preliminary data is not required for this award mechanism. Direct costs are 360 over three years. I'm going to go over just a couple of things now for each one of these. The first three, as I said, are pre-application invite. Your pre-application is due on June 20th. You will get invited by, at the latest, August 1st. That gives you little bit, about six weeks or so, maybe seven in order to get your full application in by September 26th. The Career Development Award, your pre-application or your LOI is due on August 28th, and your application submission deadline is due September 12th.

Now, one of the things people often ask me is, "**How am I supposed to make this militarily relevant?**" It's cancer. Everyone gets cancer. Cancer doesn't discriminate." Okay. We all know that. Okay? Now, I'm going to tell you how to deal with it. There's a lot of words on one side of the slide, and there's a couple of words on the other side of the slide. I'd really like you to take a look at the couple of words, rather than all those other words. It's really important, because we have two military relevant focus areas that you can choose from, and they're required for all the funding opportunities. You have to answer at least one of these, either environmental exposures or mission readiness.



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Environmental exposure is something like ionizing radiation, chemicals, pesticides, and so on. Mission readiness is really about if there is a gap in cancer care or prevention and the service member gets ill, then the mission readiness is broken for that unit. If it's not the service member, if it's a parent, or a spouse, or a child that might be ill, that person might not be 100% in the mission, and therefore mission readiness is affected. So, it's all about environmental exposures and mission readiness.

Now, in order to get into detail for those, what I suggest you do is to go to that URL I showed you, which was the CDMRP website. Go there. Go to the research programs, which is right next to the funding opportunities. Click on the research programs. Find Peer Reviewed Research Program. Click on that. Once you've gone onto the Peer Reviewed Cancer Research Program webpage, the next thing you want to do is you want to go to the right hand side, and you'll see an icon, a picture with a service member with a child in his arms. Click on that. Within that you will find information on these two militarily relevant focus areas.

If you go back to the PRCRP webpage, you'll see exposures, a link for exposures that are linked to the military experience. Go ahead and click on that. That'll give you more information. Now, if that's not quite enough information, scroll down a little bit, and find the reports to Congress. Open up the reports to Congress, and the reports to Congress, I specifically delineate some of the military relevance of some of our research, and you can look over that as well. You have a lot of different resources at your hands.

Let's talk about some general strategies and components for a successful application. There's a lot of words on this slide. I'm going to get to the nitty-gritty of it by focusing down at the very bottom. It says, "Read the program announcement carefully." The program announcements are boring. I'm going to tell you straight out, they're boring. Okay? I wrote them. I know. So, what you really need to do is you need to look at throughout the entire program announcement. You need to read it from the front to the back. Take breaks. You're going to need it, but you're going to read it from the front to the back. You're actually going to print this out. You're going to use the highlighter. You're going to use tabs. It's going to be the old fashioned way.



Strategies for Success

Components of a Successful Application



what the peer reviewers are going to do and what the programmatic reviewers are going to do, because right there is the criteria that the peer reviewers are going to use.

If you'll notice, under the project narrative, for instance, you'll notice, "Describe your alternative strategies. Describe your power calculations," yada, yada, yada. All of that type of things are written there. Tell us your hypothesis, and your objectives, and aims, and all of that. So, you'll see that that's all written in the project narrative. If you go over to the area, for instance, in the Idea Award With Special Focus, if you look under the scientist merit section, you will see that each one of those words that we tell you what to do have now been turned into a criteria.

We've taken each sentence and turned it into a question for the peer reviewers. If you miss one of those sentences, you've essentially given the peer reviewer the weakness that they need to point out. Really important to read throughout the entire program announcement, because it will tell you what you need to add. Okay? Pay attention to your eligibility requirements. That's really an important thing, as well as the deadlines. The deadlines are right on the front cover of the program announcement, not only the date, but the time. The times are important as well.

What you're going to do is you're going to look at that award information. You're going to get an idea of what the intent and the adherence to the award mechanism might be. Then you're going to go and you're going to look at the project narrative and the application package, which you need to put in there. You're going to take a real good look at that. You're going to circle things in there. Then you're going to keep on reading, even after you've submitted. Okay. Not after you've submitted, but after you've read where it says to submit. You're going to keep on reading and read all the way to the back, where it says

Applying for a Grant

Understanding the goals of the program, intent of the award mechanism, and review criteria is critical for a successful grant application

- ◆ The announcement (PA or BAA) contains information on:
 - ❖ Program Goals
 - ❖ Focus Areas
 - ❖ Award Intent
 - ❖ Required Elements, Eligibility, and Funding
 - ❖ Review Criteria
 - ❖ Deadlines

Single most important tip:
Read the announcement carefully



- ✓ **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

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Some strategies for success. Align the proposed work with the specific guidance from the program announcement. If we're looking for something that's hypothesis driven, make sure it's hypothesis driven. If we're looking for something that's really spectacularly innovative, like in the Idea Award With Special Focus, show us how it's spectacularly innovative. We're looking for impact. All of these really look for impact. The Impact Award is especially important, where we're looking for critical areas within cancer research and cancer care that needs to have that push towards an impactful difference. Innovation, as I said, is in the eye of the beholder. Show me how it's innovative. Don't just tell me.

Finally, **feasibility**. Feasibility is really an important part of this whole process. Don't go into a lot of jargon, but really tell us the expertise that you have. If you are new to bladder cancer, but you really want to get into it, make sure you have a bladder cancer collaborator, and make sure they've written a letter of collaboration to come with feasibility you. Make sure that there's time appropriate on that budget and justify it. If you are doing something with a number of animals, and you're doing a study, make sure that it's appropriately powered.

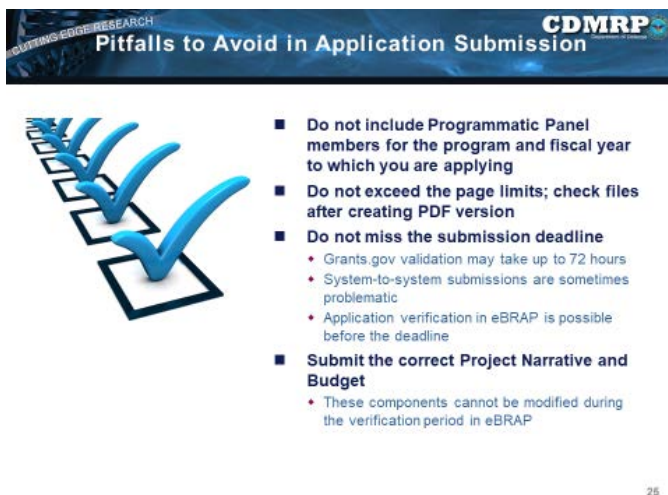
Don't tell me that you're going to go, and you're going to talk to the bio statistician that's two buildings over, and that you're going to go over and talk to him, and he's going to give you some pointers maybe over lunch one day. No. Okay? Bring that person on. They're part of the team. Bring them on, and make sure that their bio sketch is added as well. Make sure that you have access to the critical resources, reagents, and/or study populations that you might be using. If your institute doesn't really do a lot of bladder cancer, reach out. Reach out and find somebody that'll work with you and help you with those critical resources and reagents, especially if you're an early career investigator.

I've already talked about where the milestones and timelines are. Make sure you follow the rules. If you come in at 5:01 instead of 5:00, there's not much I can do for you. I know that sounds terrible, but if I let somebody in at 5:01, why don't I let somebody in at 5:02? It's just a minute later. So, we're very, very strict about these things. This is the DoD, so we're very, very strict about these things. This is how the rules go, and we have to follow them. When you are writing a long application, make sure it's clear, and don't put lots and lots of jargon in there. Nobody needs to read that, and nobody wants to read that. It makes it very difficult and tiresome for the peer reviewer. You want to make sure they understand your point that you're trying to get across.

Make sure that you **write the lay abstract in plain language**. The lay abstract is what the consumer uses. If you write it with a bunch of jargon, it's not going to help anybody. Then finally, I really want to talk about being compliant. Don't break the rules for deadlines or the requirements. If you're not an early career investigator, if you're like 20 years out from your terminal degree, and you didn't do a 10 year residency, you're probably not, you know, in the spirit of the award mechanism, so find a different award mechanism.

Okay. Some pitfalls. Programmatic Panel members for the year. Okay? Once again, go to the PRCRP website, and you can find the Programmatic Panel members. *The Programmatic Panel members must not be part of your application*. Do not put them on your application at all. Dr. Inman is on our Programmatic Panel. He is a bladder cancer expert. Brant Inman, do not put him on your application at all. If he's on the application, I will have to kick it out for being not compliant.

Don't exceed the page limits. One of the things you really want to pay attention to is that we're using ... grants.gov is now using Workspace exclusively. Make sure that you understand how to use Workspace, and make sure that all your collaborators are using the same version of Adobe. If they're not using the same version of Adobe, things could really go wonky on you in Workspace. That's an important point. Make sure that your application is put in not minutes beforehand, but a day or two beforehand, so that you have that flexibility. We do have a verification period, where you can go and you can look at what your application looks like. You can move things around. You can change things up. The only thing that you cannot change is the project narrative and the budget after the submission deadline, well, before the verification deadline.

A graphic titled "CDMRP Pitfalls to Avoid in Application Submission" with a blue header and a list of four main points, each preceded by a blue square bullet. To the left of the list is a graphic of a row of blue checkmarks in boxes. The points are: 1. Do not include Programmatic Panel members for the program and fiscal year to which you are applying. 2. Do not exceed the page limits; check files after creating PDF version. 3. Do not miss the submission deadline, with sub-points: 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. 4. Submit the correct Project Narrative and Budget, with sub-points: These components cannot be modified during the verification period in eBRAP.

CDMRP
Pitfalls to Avoid in Application Submission

- Do not include Programmatic Panel members for the program and fiscal year to which you are applying
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 - These components cannot be modified during the verification period in eBRAP

Once again, you can go to the CDMRP website to see what's being added on a daily basis for program announcements. The website URL is at the top. If you look right under ... on the left hand side, you'll see right under the word CDMRP, you'll see the research programs, and that's where you'll go to click on that in order to go to the Peer Reviewed Cancer Research Program. Thank you very much for your time and attention today. I really did enjoy speaking to you today about the Peer Reviewed Cancer Research Program and things that you can do to ensure a successful application.



Questions & Answers following the Webinar

Is there anything they should do to identify that they have the other award or any advice they should follow?

No. They don't have to. The Idea Award With Special Focus, you're only allowed to apply up to one pre-application per PI. Okay? So, there's a small caveat on that one, but all the other ones, if they want to come in and apply to each and every one of these, they can. It just has to be a different project. You cannot apply over the different funding opportunities with the same project.

Does the immunotherapy topic area include studies aiming at determining clinical response or toxicity after therapy with checkpoint blockade?

Sure.

As a PI who holds a current CDMRP Career Development Award, would previous DoD funding be looked at as favorable or unfavorable factors by a Programmatic Review Committee?

I think it depends on what they're applying for. If they're applying for another Career Development Award, is that in the intent or the spirit in the award mechanism itself, since you already are being career developed? If you have a Career Development Award from the CDMRP, whether it be from ours or one of the other many programs here at CDMRP, and you come in and you want to apply for the Impact Award or the Idea Award With Special Focus, for instance, that would be fine, because it does show that you are moving along in your career and that you are a success.

Is a foreign participant allowed, somebody from outside the United States, allowed to apply for these funds?

Yes.

For the Translational Team Award, can we propose a clinical trial? We recently completed a pilot trial and want to expand it to another site.

Yes. You can propose a clinical trial with the caveat that there has to be a major portion of the work that you're going to be funding has to be about doing work at the lab bench to understand what you're getting out of that clinical trial. You can put funds towards a clinical trial. It just can't be the sole purpose of the project.

Are the Team Science Awards allowed to include recipients, PIs, of prior awards?

Yes.

What is the timeframe from the application to receiving the Career Development or Idea Award in general?

I can tell you that we are hoping to have the recommended for funding list out by the end of February 2019. That would mean that negotiations will start sometime in March. Our acquisition authority always says that all of the money must be obligated by September of that year, but most of the time it gets done before then.

Where is the military relevance information on the CDMRP website? Can you provide the URL or show us in the webinar? How can I get to the website?

Just put in CDMRP in your favorites search. There is no need to type ".gov" following it. The Army.Mil one. It's the Army.Mil one. Okay. Go down. Click on that. Yes. Now, see underneath where it says CDMRP? Scroll up a little bit. See where it says, "CDMRP," there?

Click there. Then scroll all the way down. It says, "Peer review cancer," at the bottom. All the way down that list. Click on that. See, there's an icon of that ... Don't open anything up here. Okay? There is an icon of a soldier with a child on his back. That's the program book. That'll have information. Then there's also, underneath that big paragraph, it says, "Exposures related to cancer risks." That's one area. If you scroll down a little bit, you will see down there it says, "Annual reports to Congress." You can click on that, and that will give you more information as well.

Is there someone who could be contacted prior to an application to review whether my idea meets the programmatic requirements for a mechanism?

No. We do not do that.

Would that be something more you would sort of outsource and share your ideas with other people to see if it fits?

Yes.

Under Career Development, does a fellowship count for the 10 years? Also, if one is an associate professor or a clinical scholar, does this preclude the person from being eligible?

Okay, under Fellowship, it depends on what the fellowship is. It gets a little bit vague and wonky when we get into fellowships that might be clinical fellowships. It depends on whether or not you were at the bench or not. If you were at the bench, it does not cut out from those 10 years, but if it was a clinical fellowship where you were in the clinic all the time, you can take that out. You have to make that perfectly clear in your bio sketch.

If one is an associate professor for clinic scholars, does that preclude them from being eligible?

I mean if you are an associate professor, and if you're more than 10 years out. I don't know. It depends on where you are. Associate professor seems a little bit more mature, as far as in your career development plan, so it might not be the best fit. I would suggest you probably look at the other ones. They might be better for you.

I just want to clarify, the CDA PI eligibility for those of us who completed a medical degree, residency, clinical research fellowship within 10 years after completion of terminal degree clause starts counting from the end of medical school or from the end of fellowship?

It depends on what the fellowship is, once again. If the fellowship is a clinical fellowship, where you are working to learn something, I might not be counted within that 10 years, but if you're actually at the lab bench, I does count. If it's like a Post Doc, it counts within those 10 years.

Is collaboration with the VA hospital or the Department of Defense Institution, is that required or encouraged?

It's encouraged.

Can NIH PIs apply, and what are their chances compared to extramural PIs?

They can apply, and their chances are just as equal as anyone else's.

Where is the information on the letter of intent format, and how should it be submitted?

That's in the program announcement. There's a step by step guide in the program announcement. It actually says, "Step 1."

The Program announcement is funding opportunity. Go to

Funding opportunity.gov. then you can pull the application package down from Grants.gov and get that information as far as the format for the letter of intent.

Are there any annual progress reports to be submitted once you're given an award?

Yes. On a yearly basis, you do have to send in a progress report, and some of the more complicated award mechanisms do require quarterly reports.

The Impact Award is a new mechanism this year. How many do you anticipate giving, and can you highlight the differences between that and an RO1?

The Impact Award really is trying to support hypothesis driven, high impact research. What we're really looking for here is a continuity of research. Clinical applicability is really important and leveraging clinical samples and trials. What we're really trying to do is accelerate clinical applicability here, so we do not want to have basic research here. We're looking for impact as a critical component, transformative research, where we're really trying to leap frog the cancer field forward by utilizing previous research findings. You must have, of course, preliminary data. How many we were going to give? This is all within the program announcements that you can find on Grants.gov, as well as other funding opportunities within the CDMRP website. But we are planning on funding at least nine Impact Awards.

Can one be funded as a PI for a CDA and as part of a TTSA for the same funding cycle if the projects don't overlap?

Yes.

In the Career Development section, do we need to get support letters or collaborator letters if there's not a lot of preliminary data?

Yes.

You talk a lot about work in the lab. Is there an interest in health services research?

Yes. There is. There's actually a good interest in the idea of getting more survivorship information as well. I think in the TTSA, which is the Translational Team Science Award, we're really looking for this and strongly encouraging studies investigating patient reported outcomes, survivorship, and quality of life.

Conclusion from Dr. Kimbark:

I just want to make things perfectly, perfectly clear, so people don't get led astray. When you go to the CDMRP website, you have to click on funding opportunities to get to the program announcement or the funding opportunity award mechanism. Okay? That's where you have to go. Do not go to the PRCRP webpage looking for the funding opportunity or the program announcement. That's not where you will find it. You'll find it right there on that page. If you scroll down, you'll see the peer review cancer is on that list, if you can find it. You'll see it. You have to scroll down. There they all right there. There's the program announcement with the application instructions. You can either go here, or you can go on the www.Grants.gov website.