



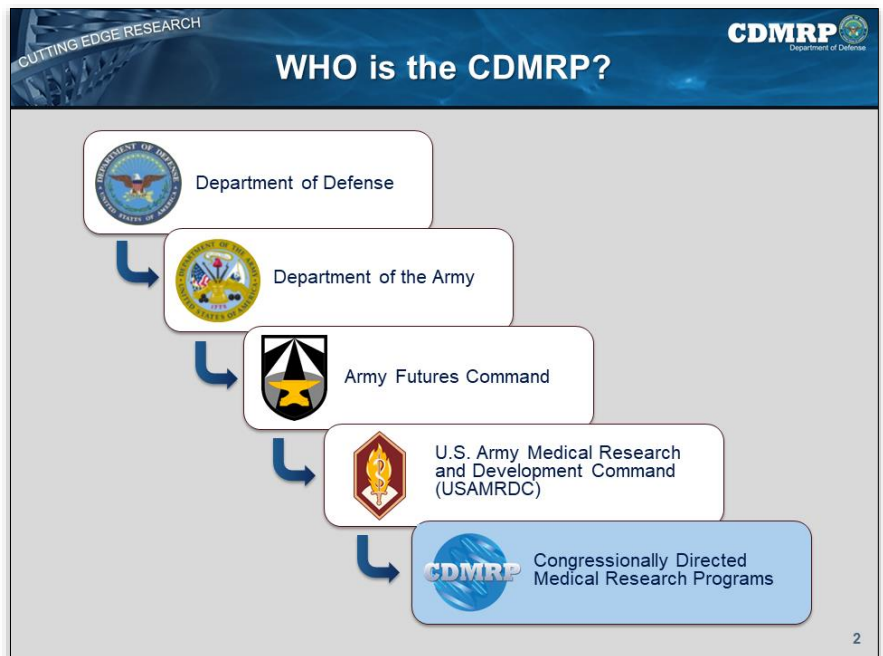
Introduction

Stephanie Chisolm: Hello and welcome to the Bladder Cancer Advocacy Networks Congressionally Directed Medical Research Program, Peer Reviewed Cancer Program for 2021. Today's program is really intended to provide an overview of how to apply for research funding within the 2021 Congressionally Directed Medical Research Program. I welcome Dr. Amie Bunker, a science officer with the Peer Review Cancer Research Program and with the Congressionally Directed Medical Research Program. Dr. Bunker has been in this role for six years managing grants in a variety of cancer areas, including all of the bladder cancer awards that kicked in starting fiscal year 2016.

We're very thrilled to have more and more interest in those research proposals. Prior to arriving at CDMRP Dr. Bunker was a postdoctoral fellow in a systems biology lab at the NCI, where she studied the regulation of P53 control genes and her response to different... in their response to different stimuli. In 2012, Dr. Bunker earned her PhD in pharmaceutical sciences from the University of Colorado, Anschutz Medical Campus. Dr. Bunker it's a pleasure to have you here

About the Peer Reviewed Cancer Research Program

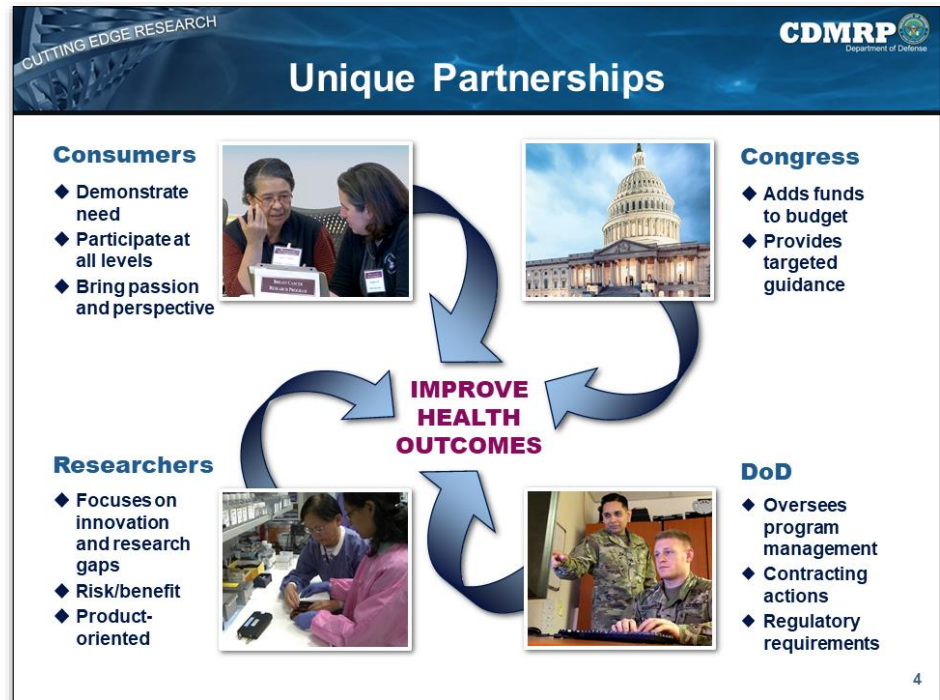
Dr. Amie Bunker: So thank you very much Stephanie for that introduction, I am very excited to be speaking with everyone here today, so without further ado I will jump right in. As she mentioned I am a science officer for the Peer Reviewed Cancer Research Programs at CDMRP. Before I jump into what most of you are here for and learning about our funding opportunities, I really wanted to give you a little bit of perspective of who is CDMRP, what are our values and what are we trying to accomplish through the PRCRP, the Peer Reviewed Cancer Research Program. We fall under the Department of Defense, on this slide I'm not going to belabor the point but you can see our chain of command and



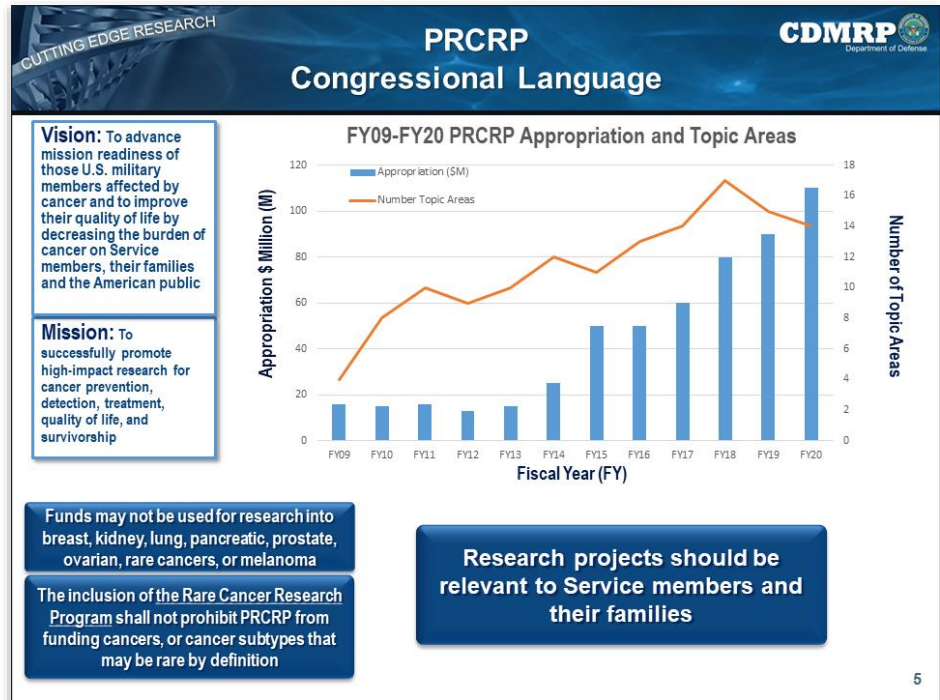
with the Congressionally Directed Medical Research Programs there at the bottom. As an office, as CDMRP our goal is to transform the health care for service members and the American public through innovative and impactful research. We do this by responsibly managing collaborative research that discovers, develops and delivers healthcare solutions for service members, veterans and the American public.

I wanted to highlight a couple of things that I think make us a CDMRP unique as far as federal funding agencies go. For starters, we get our funding directly from Congress. So if you wanted to torture yourself and go into any given years funding bill, you could actually find a line item for say the Peer Review Cancer Research Program and the appropriations that we're getting that year. So we're getting our funds directly from Congress. They come to us through DoD. We of

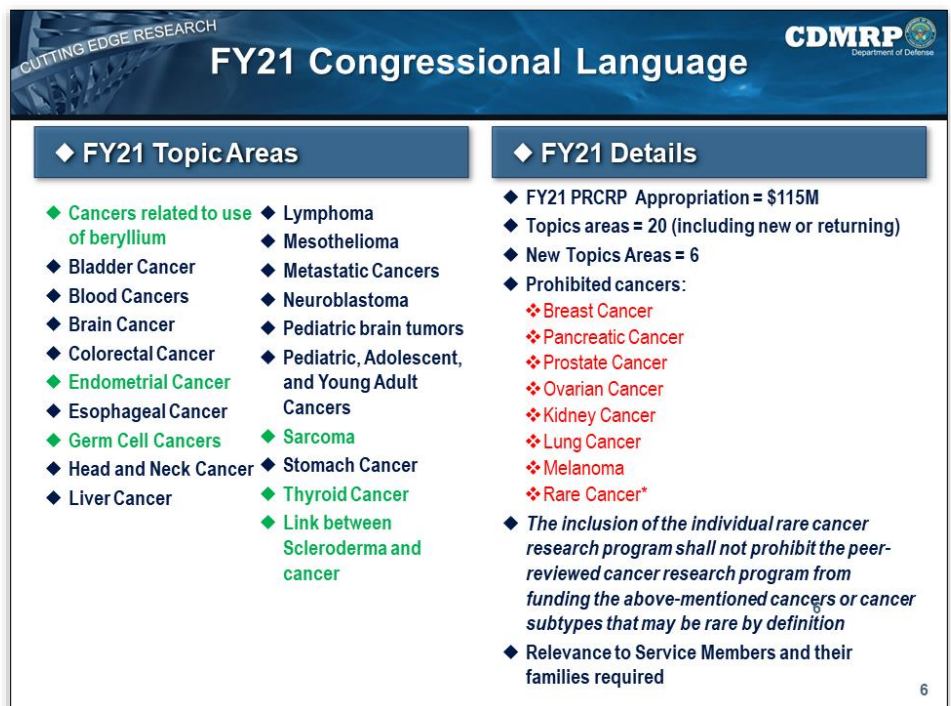
course would not exist as a program without you, the researchers who are applying for our funding and that fourth cornerstone in the top of the slide there the consumers, that really I think makes us the most unique out of the other funding agencies in that patients, caregivers, family members of people with the various conditions and injuries and diseases that are funded through the CDMRP, those people serve as active participants every facet of our review cycle. And so it's important as applicants and future awardees of us that you really do keep those in mind because we pay very close attention to their needs as a community.



The PRCRP has existed as a program since fiscal year '09. You can see from the graph in the middle here that we've been steadily growing as a program, particularly over the last five or six years. And the number of topic areas as you can see on this orange line, has also continued to more or less grow over the years. As a program our vision is to advance the mission readiness of those US military members affected by cancer, and to improve their quality of life by decreasing the burden of cancer on service members, their families and the American public.



Again, we do this by successfully promoting high impact research for cancer prevention, detection, treatment, quality of life and survivorship. I mentioned that as CDMRP and PRCRP also we get our funding directly from Congress, and that means that Congress will actually include in the funding bill each year specific language that to some degree directs us as a program as to how we are going to use our funds. And some of the highlights of that language is presented for you down at the bottom of the screen. First and foremost, we as a program



are directed by Congress that we cannot use our funds to fund cancer research into breast, kidney, lung, pancreatic, prostate, ovarian cancer or melanoma. So if your application has research... proposes research in any of those areas, those are grounds for us to administratively withdrawal that application.

There is another program that's new as of FY20. It's called the Rare Cancer Research Program and of course as many of you may appreciate, many of the cancers that are topic areas under a PRCRP are by their definition rare cancers. So there may be an occasional overlap of one cancer being applicable to both programs. So that's getting into minutiae that you don't need to concern yourselves with today, just make sure that when you're applying for PRCRP funding that you're following the instructions in our funding opportunities. And the final point I want to draw your attention to on this slide is this box here that says research projects should be relevant to service members and their families. And if you have never applied to our funding for the PRCRP you might not know exactly what that means, and I will give you a little bit more information here today while also pointing you to some resources that you can look up after this webinar today and get some more information about that, what that means to us in our program.

As I mentioned Congress tells us each year which specific topic areas that we're going to be investing our appropriation in. So for FY21 we have \$115 million and Congress has given us a list of 20 topic areas that we are going to use that \$115 million to fund research in. All 20 of those topic areas are listed here on the left. The topic areas in green are the ones that are new to our program for FY21. As I said on the previous slide pay particular attention that when you are submitting an application that it is one of these topic areas. So as this is a webinar for the Bladder Cancer Advocacy Network, I would expect most of you wouldn't have any problem since bladder cancer is one of those topic areas, but just again being mindful that any of the other topic areas that are prohibited such... in particular which might be of interest to this group particularly prostate, kidney cancer and any of these other cancers. No funds from our program can be invested in those cancer types that are listed over here in red.

The reason we are prohibited from using our money to invest in these cancer areas is because they have their own research program. So Congress has already designated a pot of money for breast cancer research, that's the Breast Cancer Research Program. For pancreatic cancer, there's a Pancreatic Cancer Research Program and so on and so forth. So in Congress's interpretation that if we were to fund anything in those topic areas we would essentially be double dipping so that's why those are excluded. Thank you.

Grant Topic Requirements

Dr. Amie Bunker: So I've mentioned the military relevance of our applications and so here's where I'll give you some more information about that. So to help applicants address the congressional intent for that statement, we as a program have developed two Military Health focus areas that are listed on the screen. The first one is environmental or exposure risk factors associated with cancer. So things like ionizing, radiation, infectious agents, environmental carcinogens that service members may be exposed to in the line of their active duty. And then the second one is mission readiness. And what that means is... to us as a program and as

we've defined it with the help of service member advisors to our program, is that for example if a service member is part of a unit that's deployed, and they receive a diagnosis that they have cancer. Well, they have to then leave their units to go seek treatment, they may or may not ever return to their unit depending on whether they're ever able to regain fitness for returning to duty.



So as a consequence of that service member receiving a cancer diagnosis, they are negatively affecting, negatively impacting the mission readiness of that unit. That unit is no longer able to function as it had when they had that member. So when we're asking you to address mission readiness, really think about how would your research eliminate or alleviate that negative impact to a unit. So this is really just a very high level, very quick introduction to these Military Health focus areas. I do also want to mention that every application must address at least one of these.

So to help you prepare and learn more about what those mean to us as a program and how you can address them in your application. You can start by finding more information going to the video that... the link that is listed at the bottom of this slide, and that'll go into more of what these are and what they mean to us, this program. Also, when you go to the specific funding opportunities, there is a section in the program description section of the funding opportunity that lists the Military Health focus areas there and provides additional resources that are available on the CDMRP website and reiterate where to find this video that's listed at the bottom of this slide.

So definitely this is... I'll mention this again later but this is something that is very important to our program and if... I have seen applications that if they do... that if the applicants do not adequately address one of these health focus areas, then they may not get selected for funding if there is an equal comparable applicant who has given better thought, more thorough attention to these focus areas. So I encourage you to make sure that you pay attention to those.

CUTTING EDGE RESEARCH **FY21 Congressional Language: Relevance to Military Health Focus Areas** **CDMRP**
Department of Defense

Required for All Funding Opportunities

- ◆ **Environmental/Exposure risk factors associated with cancer (e.g., ionizing radiation, chemicals, infectious agents, and environmental carcinogens)** → 
- ◆ **Mission Readiness** → 
❖ Gaps in cancer prevention, early detection/diagnosis, prognosis, and/or treatment
❖ Gaps in quality of life and/or survivorship

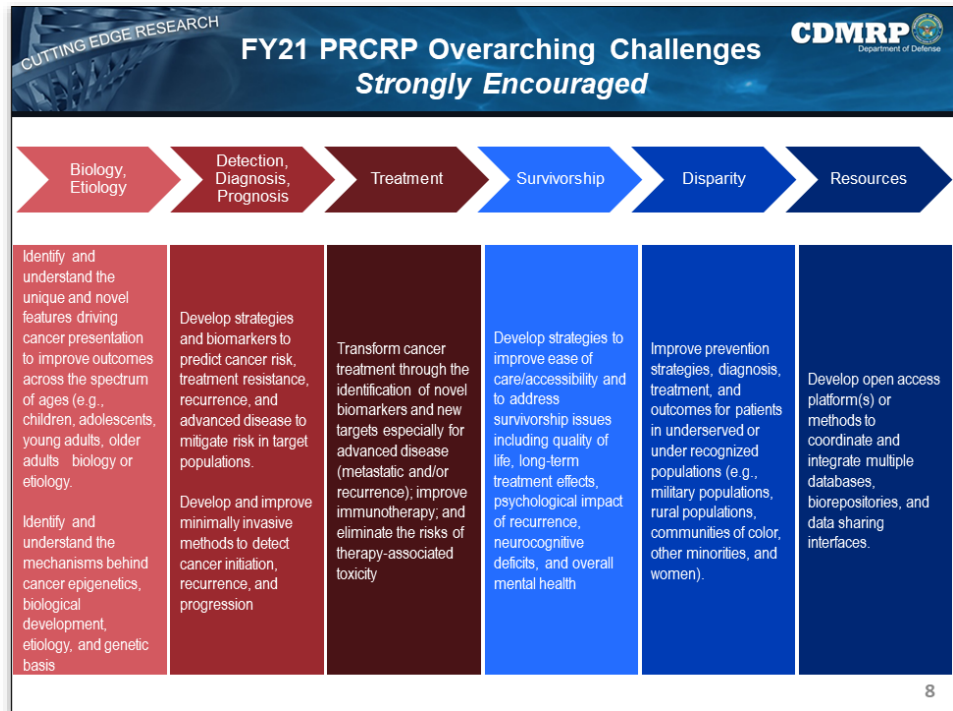
Environmental Exposures

Mission Readiness

For more information: <https://youtu.be/g3TiEf97Ch0>

7

So that was the Military Health now moving on, another item that is new to PRCRP for FY21 are the PRCRP overarching challenges. I'm not going to read through every challenge that's listed on this slide. Once again they are listed in each funding opportunity, and you will be strongly encouraged to choose one of these gates overarching challenges, and describe how your proposal, how your application addresses at least one of these. If you choose not to select one of these overarching challenges then you will



be required to justify why your research is still impactful. And what you can see... what I will describe is that these overarching challenges, they aligned to what we refer to as a cancer care spectrum. So it starts over on the left at basic biology etiology, understanding how does a particular cancer arise? What are the mechanisms that drive its progression and so on?

We have detection, diagnosis, prognosis so what can we do to improve these areas for our patients? Treatments is self explanatory. Obviously, not every cancer patient responds equally well if at all to the available options so what can we do to make better treatments available to more patients? Survivorship is... again once someone... if they are treated successfully for their cancer and they are in remission or longer, that treatment, that diagnosis still impacts their lives. So how do we do more to treat the patient as a person not just the cancer diagnosis. And finally resources, almost every cancer area could benefit from better models, more repositories, etc. So what about your application might be able to contribute to the field new resources. And before moving on into the... what you probably all came here about to learn more about the specific funding opportunities. Just wanted to give a little snapshot of what we have done for bladder cancer.

Most of you I'm sure can appreciate bladder cancer is the fourth most common cancer diagnosed in the VA Health System. Due to the high recurrence rate and the expensive nature of the sufferance methods to track cancer patients... bladder cancer patients and survivors, it's known as one of the most if not the most expensive cancer to treat. And as of 2016 there were over 765,000 bladder cancer survivors in the US so there's clearly a need for the... Having a bladder cancer and having it be a topic area under the PRCRP at the least. As mentioned at the beginning of the talk bladder cancer has been a topic area for the PRCRP since FY2016. Since then between FY16 and '19, we as a program have invested \$23.9 million into bladder cancer research, which amounts to 39 awards. The FY20 Awards are currently undergoing negotiations, so these numbers may be subject to some variability, they're not set yet but as of this time we have invested \$7.8 million into bladder cancer research which is nine awards.

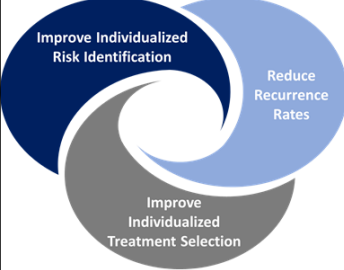
As part of our research as a program we've identified some patient care gaps in bladder cancer research that are involved... revolve around improving individualized risk spread stratification, trying to reduce the recurrence rates in bladder cancer patients and then just overall improving individualized treatment selection for the bladder cancer patient community. And on the lower right hand corner here is just a snapshot of some of the projects that we funded. The top one is Dr. Brandt, he received an Idea Award to look at a novel therapeutic option called Symphony. And then the lower one was a team that received a Translational Team Science Award, Dr. Maya Omar, Dr. Shilpa Gupta and Dr. [inaudible] And they're really a truly multidisciplinary team. You see here are the translational scientists, the medical oncologist and the computational biologists all coming together to work on biomarkers that can better inform clinician decisions when it comes to treating cancer, their bladder cancer patients.

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Department of Defense

Bladder Cancer (BC) and the PRCRP

- ◆ Bladder cancer is the 4th most common cancer diagnosed in the VA health system
- ◆ Due to high recurrence rates and the need for expensive surveillance measures BC is considered the most expensive cancer to treat
- ◆ As of 2016 there were 765,950 BC survivors in the USA
- ◆ Bladder Cancer designated as a PRCRP Topic Area for the first time in FY16
- ◆ FY16-FY19 PRCRP funded \$23.9M; 39 awards
- ◆ FY20* PRCRP funded \$7.8M; 9 awards

Significant Research and Patient Care Gaps in BC

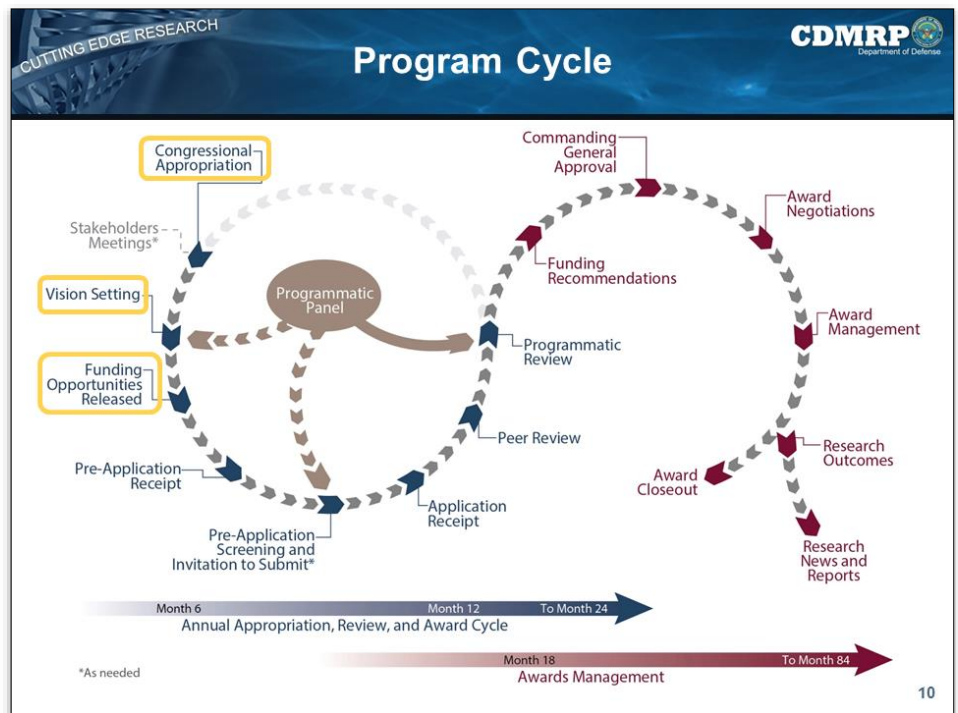


| PI/Organization | Goals |
|---|---|
| Dr. Brant Inman, Duke University | Developed a novel combination cancer therapy referred to as Synergistic Immuno Photothermal Nanotherapy (SYMPHONY) by integrating plasmonic gold nanostar (GNS)-mediated photothermal therapy with anti-PD-L1 checkpoint inhibitor immunotherapy to improve efficacy of BC treatment. |
| Dr. Mian Omar Dr. Shilpa Gupta Dr. Tae Hyun Hwang, Cleveland Clinic | This multidisciplinary team, consisting of a basic/translational biologist, bladder cancer oncologist, and computational biologist, aim to use relevant mouse models, patient data, and Deep Learning algorithms to better understand the limitations of immunotherapy in bladder cancer patients and develop tools to aid clinicians in selecting the best options for their patients. |

*Subject to final award negotiations

PCRCP Program Cycle

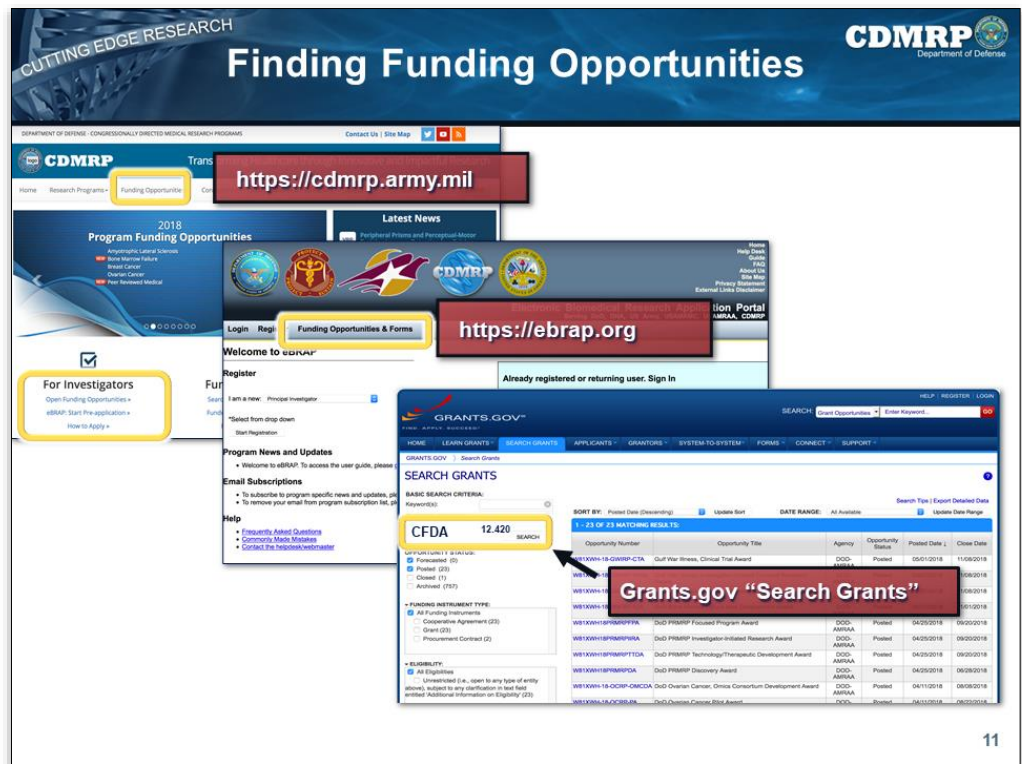
A little bit about our program cycle and how it works. As I mentioned it starts with the congressional appropriations, so we get one of those every year, it tells us how much we have to invest. We then move on to vision setting which is really our investment strategy meeting, it's where we decide which funding opportunities are going to be offered and approximately how many we intend to offer, and we take a look at our programmatic panel and I'll get a little bit more and who makes up our programmatic panel and what they do but they're a diverse pool of researchers that are experts in the topic areas that are funded by PRC, they're basic scientists, they're clinicians,



they're consumers, so patients or survivors of the various cancers that we are funding. So they take a look at the field and identify gaps and what we can do with our investment strategy to help fill those gaps and target them.

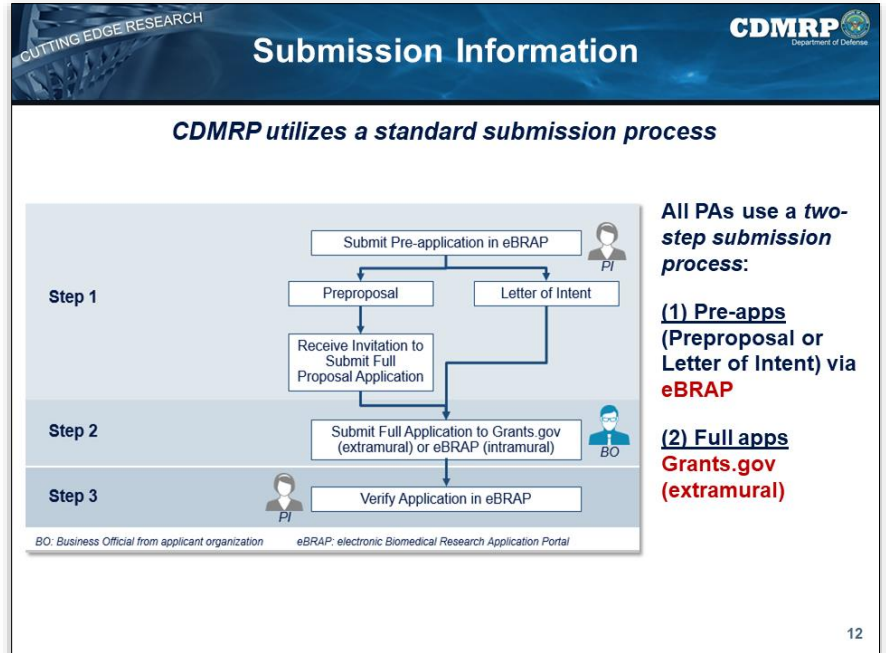
After the meeting, the funding opportunities are released, these should be coming out for FY21 any day now. At this time you can see the pre-announcements on the CDMRP website which will give you a snapshot of the funding opportunities that are going to be available. And again keep that on your radar that the full funding opportunities will be coming out very soon. And then we go through a pre-application phase, peer review, programmatic review and then the awards go into the negotiation and active award phase. To find our funding opportunities there are three locations that you can look for. We do post them on the CDMRP homepage, you will see one of the banners that cycle through will say... in the case for now it'll say 2021 program funding opportunities and a list of all the programs that are currently accepting applications. You can go to the tab that says funding opportunities or the four investigators section to go find specifically what is available at that time.

You can also go to ebrap.org, you will see the tab there for funding opportunities and forms. Another point of note on eBRAP is that you can go down to subscribe to email subscriptions. And so if you haven't done that already I encourage you to do so because then you will be notified by email when the funding opportunities for the programs that you select are available and any other news and noteworthy items that may become available to you. And finally you can go to grants.gov and search there.

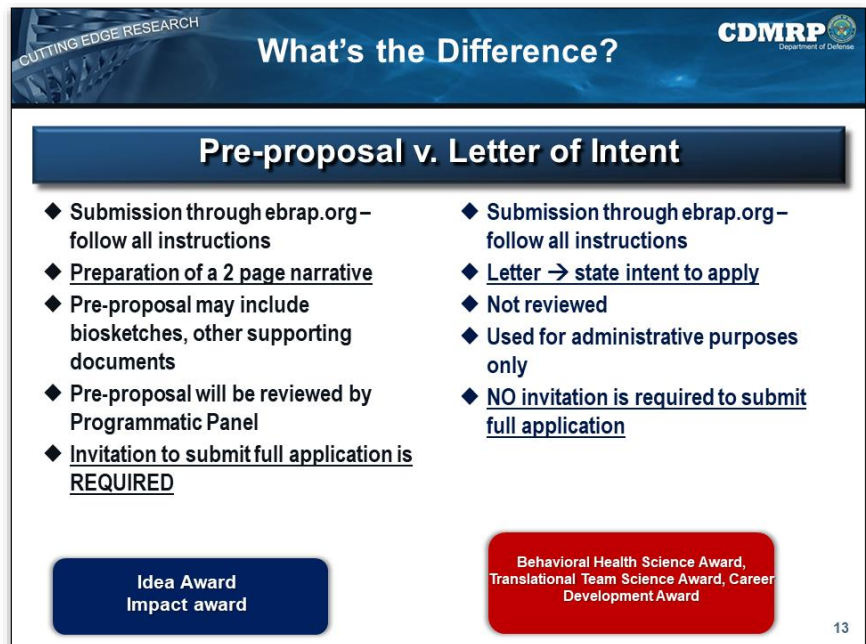


CDMRP uses a standard submission process across all of our programs, it is a two step process. There is a pre-application phase where these are either pre-proposals or letters of intent, and I'll go into the distinction of those on the next slide, these are submitted through eBRAP. And then the second phase is the submission of the full application through grants.gov. And I want to say that these... the pre application phase that is submitted to eBRAP is a requirement for all applications, whether it is a letter of intent or a pre proposal, one of those two things are going to be required. If you do not submit a pre application then you will not be eligible to submit a full application.

So what's the difference? If you see that a pre-proposal is a requirement of a particular funding opportunity, again these submissions are through eBRAP, the funding opportunity will provide the specific instructions that you need to follow to submit the pre-proposal, make sure you follow all of those instructions. They are generally preparation of a two page narrative. You can include proposal, bio sketches, other supporting documents as instructed. This will be reviewed by our programmatic panel so that diverse panel of experts on various cancers that are funded through the PRC, they will go through these and they will decide which pool of these pre proposals are going to be invited to submit full applications.



This would be a great place where you're expected to address the overarching challenges that I mentioned in previous slides, this would be one of those places, and it's really giving them a chance to see okay is this project sounds like it's going to address the intent of this funding opportunity. And these are required for the PRCRP's Idea Award and for the Impact Award. And I will go into each of these specific funding opportunities over the next several slides. So that's a pre-proposal, there's also the letter of intent. Again, these are also submitted through eBRAP and it's a letter simply saying that you're going to apply, these are not reviewed, they're only used for administrative purposes such as helping us get an early start on selecting peer reviewer recruitment, and you do not have... oh, I'm sorry, I don't remember if I mentioned that for the Idea Award and the Impact Award that have the pre-proposals, you must be invited to submit a full application. If you are not invited to submit a full application then you will not be allowed to do so.



The letter of intent, there's no review, there's no need to be invited to submit a full application. But you still need to submit the letter of intent, if you don't submit the letter of intent then you will not be able

to submit a full application. The Behavioral Health Science Award, the Translational Team Science Award and the Career Development Award, all three of these funding opportunities use a letter of intent.

Funding Opportunities

So getting into what you've all been eagerly awaiting for is the outline and key points of the FY21 PRCRP funding opportunities. The first of these is the Idea Award, these are eligible or open to all faculty, all researchers with a faculty level appointments. These are supposed to be innovative, high risk, high gain research. The emphasis says here is really on innovation, this is not meant to be a continuity of research type of proposal. You do not have to include preliminary data but if you do include preliminary data in your application, then it is fair game for peer reviewers to critique it.

For this year the Idea award is going to be \$500,000 for up to three years and the key points for these again is what is the innovation? What is novel? What are you testing? Convince us, convince the panel, the peer reviewers and the programmatic panel, that this is something that if successful would be impactful. This should not be an incremental advance or a next logical research... next logical step in your research. And again pay attention to the overarching challenges and making sure that you're addressing those in your application. And as I touched on before and this will come up a few more times, is that don't fill in the Military Health focus areas, really pay attention to those.

CUTTING EDGE RESEARCH
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FY21 PRCRP Funding Opportunities

| ◆ Career Development Award - Fellow | ◆ Key Points for Success |
|---|--|
| <ul style="list-style-type: none"> ◆ Independent investigators at or above the level of Research 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 ◆ History of extramural funding not required ◆ Preliminary data not required ◆ Direct costs - \$400k over 3 yrs. ◆ 50% protected time | <ul style="list-style-type: none"> ◆ Impact → the point is to change the lives of patients with cancer, beyond only treatment! ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges ◆ Career Development Plan <ul style="list-style-type: none"> ❖ Show involvement of Career Guide ❖ Logical progression of career ❖ Milestones to further career ❖ Networking and collaboration ❖ Workshops, training, and courses |

14

CUTTING EDGE RESEARCH
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FY21 PRCRP Funding Opportunities

| ◆ Idea Award | ◆ Key Points for Success |
|--|--|
| <ul style="list-style-type: none"> ◆ All researchers with faculty level appointment eligible ◆ Supports innovative, high-risk/high gain research ◆ <i>Emphasis on innovation</i> ◆ Preliminary data not required ◆ Direct costs - \$500k up to 3 yrs. | <ul style="list-style-type: none"> ◆ Innovation <ul style="list-style-type: none"> ❖ Argue your case → Justify! ❖ Innovation is NOT incremental advance, the next logical step in your research, changing cancers ◆ Preliminary data will be evaluated if included ◆ Pay attention to the newly minted FY21 PRCRP Overarching Challenges in the Impact Statement ◆ Don't phone in the Military Health Focus Areas |

15

Then the next is the Impact Award. This is for assistant professors or above and this is... as the name of the funding opportunity implies something that really if successful again and is going to have a major impact on the field. Funds for this award can be used for clinical trial costs, you are required to provide preliminary data and the direct costs for this funding opportunity is \$1.25 million over the course of three years. Therefore to be successful applicants for this funding opportunity, you really want to be clear and tell the

reviewers why this proposal is going to be impactful. By near term we're talking about within five years what is this research going to do for our patient community? Again, make sure you're addressing one of the overarching challenges and this really is meant to be a continuity of research, and at the end of... part of the application is a research outcomes plan. So you're telling us your vision for this project, when this project is complete this is how you see the next steps progressing.

So if it is supposed to be preclinical work testing, efficacy, toxicity etc of a novel therapeutic target or novel therapeutic how are you going to then advance it once this award is done to the next level? Show us that you have a plan for where you're going with this project, and what's your plan and why is this research distinct.

The next one is the Translational Team Science Award, eligible applicants are at the assistant professor level or above, and this is really to fund at least two but no more than three partners. It's hypothesis driven correlative research and those correlative research have an either completed or currently ongoing clinical trial. You can use funds from this award to support a clinical trial, however that's not the intent of what we're trying to accomplish with this. It's

CUTTING EDGE RESEARCH **CDMRP** Department of Defense

FY21 PRCRP Funding Opportunities

- ◆ **Impact Award**
 - ◆ Assistant Professor or above eligible
 - ◆ Support research that demonstrates the potential to have a major impact in the near term on an area of paramount importance in cancer
 - ◆ Clinical Trial support allowed
 - ◆ Preliminary data required
 - ◆ Direct costs - \$1.25M over 3 yrs.
- ◆ **Key Points for Success**
 - ◆ Impact should be clearly stated how it will be near term
 - ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
 - ◆ Continuity of Research → Research Outcomes Plan
 - ❖ Einstein thought experiment for your outcomes/future plans
 - ❖ Why is this research distinct and should be funded for future patient outcomes

16

CUTTING EDGE RESEARCH **CDMRP** Department of Defense

FY21 PRCRP Funding Opportunities

- ◆ **Translational Team Science Award**
 - ◆ Assistant Professor or above eligible
 - ◆ 2-3 PIs partner
 - ◆ Supports hypothesis driven correlative studies associated with an ongoing or completed trial
 - ◆ Clinical Trial support
 - ◆ Preliminary data required
 - ◆ Direct costs - \$2.5M amongst the partners over 4 yrs.
- ◆ **Key Points for Success**
 - ◆ Collaboration → clearly show why and how all investigators are critical to the success
 - ◆ Translation → the bench should inform the clinic
 - ◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges
 - ◆ Research Outcomes Plan
 - ❖ Einstein thought experiment for your outcomes/future plans
 - ❖ Why is this research distinct and should be funded for future patient outcomes

17

really you have a clinical trial study, you have a pool of specimens and you're trying to understand why some people responded to the therapy and why others didn't, something of that nature or similar.

Again, you must provide preliminary data and the direct costs for FY21 are going to be \$2.5 million across two to three partners over four years. Again, collaboration is one of the key points of emphasis for this project. So clearly show how each partner is intellectually involved in the project. This is not meant to be a partnership between a translational scientists and a clinician where the clinician is only providing samples and that's it. We want to see where the clinician is involved in the design, the analysis, the interpretation and then advancing the outcomes forward. So really show how it's a partnership not just someone's... my neighbor is giving me samples from down the hall. And again as the name of the funding opportunity implies, we want to see the translation. So you have a clinical trial, you're bringing ideas back to the bench and how are those going to then be translated back to the clinic?

Be mindful about including one of the overarching challenges again, and the Translational Team Science Award also requires research outcomes plan as part of the proposal. So again if this project is complete where do you see the next steps going and how are you going to get there?

And then the last funding opportunity that I'm going to speak to is the Behavioral Health Science Award. This was new in FY20 and they are for independent investigators with faculty level appointment or equivalent, supporting innovative research and are really addressing the three stages of survivorship, which are listed on the lower right hand corner of the slide. So acute survivorship from the diagnosis to the end of initial treatment, extended survivorship. So after treatment helping address the patient needs and then permanent survivorship, so again a lot of cancer treatments can have long term impact on the patient. What are we doing to help those patients improving their quality of life?

CUTTING EDGE RESEARCH **CDMRP** Department of Defense

FY21 PRCRP Funding Opportunities

| ◆ Behavioral Health Science Award | ◆ Key Points for Success |
|--|---|
| <ul style="list-style-type: none">◆ Independent investigator with a faculty-level appointment (or equivalent).◆ Supports innovative research◆ Three Stages of Survivorship◆ Survivorship, QoL, psychosocial effects related to cancer◆ Allows support of <i>Pilot</i> Clinical Trial support◆ Only 3 of the FY21 PRCRP Overarching Challenges are included◆ Preliminary data required for applications proposing a pilot clinical trial◆ Direct costs - \$1M over 4 yrs | <ul style="list-style-type: none">◆ Impact → the point is to change the lives of patients with cancer, beyond only treatment!◆ Patient Advocates must be involved and should be from the cancer being studied◆ Justify how your work will make an advance for one of the FY21 PRCRP Overarching Challenges◆ Understand the 3 Stages of Survivorship<ul style="list-style-type: none">❖ Acute survivorship from diagnosis through to the end of initial treatment.❖ Extended survivorship end of initial treatment goes through the months after.❖ Permanent survivorship years have passed since cancer treatment ended. Long-term effects of cancer and treatment are the focus |

18

This mechanism also does support pilots clinical trials concepts, only three of those eight overarching challenges are applicable to this funding opportunity. If you don't select one of those three overarching challenges then again you'll be required to justify why the proposal is still a fitting area of need, and this funding opportunity is \$1 million over four years. In addition to impact and overarching challenges and adjusting stages or survivorship, a unique feature of this funding opportunity compared to the other ones I've talked about today is that patient advocates must be involved in the application itself... in creating the application, but also in the execution of the projects. So this is described in more detail in the funding opportunity so read through that and make sure you understand the intent of that. Again, as

I mentioned at the beginning of this talk we really do take the... as a program and as an [inaudible] CDMRP the perspective of the consumers very seriously. And so when you're submitting an application please be sure that you're including patient advocates that are... their advocates or cancer survivors of the cancer that's being studied.

Stephanie Chisolm: For those of you who are interested in the Behavioral Health Science Award, perhaps you have your own group of patient advocates that you have worked with in the past, but if you would like please approach me Stephanie Chisolm, the Director of Education and Research at BCAN because we have a whole group of patient advocates that have been trained and are very eager to get involved in the research process. And depending on what you're studying there may well be some people within this group that I can help you connect with to be patient advocates, to be involved in the development or implementation of your trial. So if you don't have patients on your own certainly we can help try to coordinate that for you. So please let me know.

Dr. Amie Bunker: Thank you. And while you were talking Stephanie I realized that I did actually leave a funding opportunity out of my presentation. So there is one more, it is our Career Development Award the fellow option, and so that... You can find out more information about that by visiting the PRCRP web page, and you can find it on listed with the other pre-announcement information. So my apologies for that but if you are an early career investigator, please do go seek that funding opportunity out and find out more about it from our web page. And then the next few slides are really just going to speak to reading our funding opportunities and understanding where to find the most important information.

Obviously, they're documents, they're technical in nature so they're long and they're not always... not every section is the most exciting to read, but I can't emphasize enough that the most important thing that I hope you take away from this next section is to please read all of the words from both the program announcement and the accompanying general application instructions. These are updated every year so make sure you're looking at the appropriate funding opportunity for the appropriate fiscal year. So we're going to... we're talking about the FY21 fiscal year. And on the cover of the first page of each program announcement funding opportunity, you will see the name of that particular announcement. So this one is the cover page for Behavioral Health Science Award, and very important listed right there on page one are all of the submission and review dates. The submission deadlines are for all intents and purposes final. There are very few occasions when those dates would be pushed back, so pay attention to them, add calendar invites or calendar warnings whatever you need to do, these deadlines are important.

Program Announcement

Peer Reviewed Cancer Research Program

Behavioral Health Science Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH21-PRCRP-BHSA

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 29, 2021]
- Application Submission Deadline: 11:59 p.m. ET, [August 18, 2021]
- End of Application Verification Period: 5:00 p.m. ET, [August 25, 2021]
- Peer Review: [October 2021]
- Programmatic Review: [December 2021]

General Application Instructions

Version 001

Department of Defense

Congressionally Directed Medical Research Program

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
 - F. Application Submission Overview 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 10
 - B. Submission to Grants.gov 26
 - C. Applicant Verification of Grants.gov Submission in eBRAP 26
 - D. Application Tracking 27
- IV. APPLICATION SUBMISSION FOR INTRAMURAL ORGANIZATIONS 27
 - A. eBRAP Application Package Components 27
- APPENDIX 1 REGULATORY REQUIREMENTS 35
- APPENDIX 2 REPORTING REQUIREMENTS AND ADMINISTRATIVE INFORMATION 42
- APPENDIX 3 QUALIFICATION AND RESTRICTIONS INFORMATION 48
- APPENDIX 4 FORMATTING GUIDELINES 49
- APPENDIX 5 NATIONAL POLICY REQUIREMENTS 50
- APPENDIX 6 ACRONYM LIST 53

Single most important tip:
Read both documents carefully

19

PRCRP Review Process

So the first tier of review that we have is peer review, and this is technical, merit based part of our review process. The peer reviewers are both scientific peer reviewers, so either basic science researchers, clinicians, etc. They are... again we do have consumer reviewers, so on the bladder cancer panel we're going to have bladder cancer consumers, we don't have standing panels so we do have 50 to 60% turnover every year, and they're based on their expertise and the needs of the program and you as an applicant will not know their identities and there's... you're not allowed to have any interaction

between the peer reviewer and yourself as an applicant. These peer review as we like to say it's... you're not being compared to any other applicants, your application is being compared to a gold standard so to speak, and the outcome of peer review are summary statements. So I'll go through some of example of peer review criteria on the next slide, but in each funding opportunity you will learn the funding opportunity that describes which criteria are scored criteria and which are unscored criteria.


And so you should be making sure to speak to each of those different criteria. They're spelled out in the funding opportunity and the summary statement will summarize the reviewers comments broken down by each of those criteria areas. And really the thing to keep in mind at this part is that you're writing to the peer reviewers not just to the scientists... not just to the science, excuse me.

So here on this slide is an example of peer review criteria that could be used to judge a research strategy and feasibility section of an application. And you really want to think of this as a scoring rubric, so read each of these criteria points carefully and make sure that your application addresses each one of these points. And so the score that you get for research strategy and feasibility is going to be based on how well you address each of these points. And just kind of... I'll reiterate this in a second but one of the things to keep in mind as you're addressing the criteria and developing your proposal is to keep... to try to reduce jargon and make sure that

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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 is not permitted



Outcome: Summary Statements

20

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Example of Peer Review Criteria

To determine technical merit, all applications will be evaluated according to the following scored criteria, [which are of equal importance:

- **Research Strategy and Feasibility:**
 - Whether the stated hypothesis or the objective is relevant to at least one of the FY21 PRCRP Topic Areas in [Section II.A.1.](#)
 - To what degree the study design, proposed methods, and analyses are appropriate to test the hypothesis and/or reach the final objective.
 - If applicable, for retrospective or prospective recruitment studies whether the application defines the type of study (e.g., descriptive, correlational, field experimental, meta-analyses).
 - If applicable, whether study populations are defined.
 - To what degree the application addresses potential problem areas and potential pitfalls and presents alternative methods and approaches.
 - To what extent the proposed study is innovative or is a high reward concept in at least one of the three areas of survivorship.

Answer ALL of the questions Peer Reviewers evaluate!

21

someone who's not an expert in your specific field will be able to understand the concepts that you're conveying when you're addressing each of these peer review criteria.

Then all of our applications go through a second tier of review called programmatic review. And so again this is a diverse panel for peer review, you have programmatic panel members that are experts in colorectal cancer, bladder cancer, mesothelioma and so on and so forth, across all of our funded topic areas. And so this part of review is a comparison based review, so you're being... the summary statement of your project being compared to the summary statement of another project. And this is where it's going to be very important that you have a good Military Health relevance statement. And so that's going to be one of the things that the programmatic reviewers are looking at closely. I've seen projects that they may have scored very well in peer review and they hit all of the science notes perfect... well maybe not perfect, no one's perfect. But they hit all of the notes and got a good peer review score, but they phoned in or didn't adequately address those Military Health focus areas where another high scoring proposal did do that.


And so there's only so much funding to go around and so that's... they're going to factor that into their decision making. As part of some of these applications you

may be told to submit an innovation statement or an impact statement, or something of one of those types of things. And so that is also something that the programmatic panel members will take into consideration at this point. So how well are you making the case that your project if it's an Idea Award, how innovative is it? If it's an Impact Award, how well did you make that case in your impact statements? And so the outcome of programmatic review is a list of funding recommendations, a list of projects that are recommended for funding. And getting down to the end here, a few Strategies for success is plan ahead. As I mentioned a few slides ago these deadlines are important so plan ahead, plan

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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

22

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Programmatic Panel

| | |
|--|---|
| John Kuttesch, M.D., Ph.D. (FY20-21 Chair) University of New Mexico | <p>II.E.1.b. Programmatic Review</p> <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 FY21 PRCRR, as evidenced by the following: <ul style="list-style-type: none"> ○ [Adherence to the intent of the award mechanism] ○ Program portfolio balance and composition ○ Programmatic relevance to the FY21 PRCRP Military Health Focus Areas ○ Programmatic relevance to the FY21 PRCRP Overarching Challenges ○ Relative impact] <ul style="list-style-type: none"> • 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'! |
| Dan Dixon, Ph.D. (Chair Emeritus) University of Kansas Medical Center | |
| Clark Chen, M.D., Ph.D. University of Minnesota | |
| LCDR Alden Chiu Walter Reed National Military Medical Center | |
| Paul Doetsch, Ph.D. NIH/NIHES | |
| LCDR Michelle Gage M.D. Walter Reed National Military Medical Center | |
| Adam Hayden (Consumer) National Brain Tumor Society | |
| 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-Veteran) Lymphoma Research Foundation | |
| Lopa Mishra, M.D. George Washington University | |
| Col (ret) Thomas Newton M.D. (Veteran) Inova Schar Cancer Institute | |
| Kenneth Tanabe, M.D. Harvard University | |
| Chiaojung Jillian Tsai, M.D., Ph.D. Memorial Sloan Kettering Cancer Center | |

23

accordingly, give yourself time to read the funding opportunities well in advance if you're applying because... if you're applying for the Behavioral Health Science Awards, you might need time to find appropriate consumer advocates to incorporate into your research.

So that may take time, if you've never done something like that before. If you're applying for a Translational Team Science Award, maybe you'd like to propose a new collaboration with someone that you haven't worked with before.

So you're going to need time to get that fleshed out and the appropriate letters and things of that nature into place. So planning is important.

Grantsmanship, I touched on this a little bit, really making sure that you state your idea up front and then support it, be clear. Again, you have consumers they're not reviewing the science for our proposals, but they are looking at those other statements. They're looking at the abstracts, they're looking at the Military Health focus areas. So really make sure that you're reaching out to... Particularly in those areas that you're reaching out and making the argument for why your application is hitting the needs of that funding opportunity.

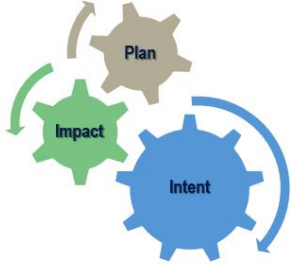
Again, intent of the mechanism, read the award information sections closely because that's where we're telling you what we're looking for. Read through all of the peer and programmatic review criteria, because we're telling you what we're looking for and how we're scoring. Address the impact, again we want cool science, we want good science but it has to be important, impactful science also. And of course feasibility, ideas are great but show us that you have the expertise and the team necessary to carry them out.

Some pitfalls to avoid, this is very, very important. Do not include current programmatic panel members in your

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Strategies for Success


- ◆ **Plan Ahead**
 - ◆ Deadlines are important!
 - ◆ Coordinate your efforts → bring the team together early
- ◆ **Grantsmanship**
 - ◆ The Ted Talk → state your idea upfront, then back it up!
 - ◆ Clear voice, forget the jargon → not a competition to see how many abbreviations included
 - ◆ Review your documents prior to submission → use the verification period!
- ◆ **What's the Intent**
 - ◆ How do you fit in → Ted Talk again!
 - ◆ Make your case to how your research aligns with the intent
- ◆ **Impact**
 - ◆ Cool science is good → Impactful science is great!
 - ◆ Show how it is impactful, important to patients
- ◆ **Feasibility**
 - ◆ Clearly define your team's skills
 - ◆ Outline your justification on how and why you can achieve the anticipated outcomes



24

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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

25

application, you can find the list of current panel members on the PRCRP website. Do not exceed page limits. Make sure you convert everything to a PDF and look through it before submitting it. Don't miss the submission deadlines and make sure that you submit the correct project narrative and the correct budgets. Once those are submitted and the deadline is passed, those cannot be modified during the verification period in eBRAP, so be very careful with those.

For the FY21 PRCRP timelines, these I'm not going to read all of these here you're going to have the slides. So pay attention to those, pay attention to again whether you're applying to an Idea Award or an Impact Award and you have to submit a pre proposal, or if you're applying to the other mechanisms that only require a letter of intent, and the deadlines that are associated with each of those items. And finally please visit the PRCRP website and you can find information again about funding opportunities, you can see lists of recently funded investigators, we have what's called information papers that give you some statistics about submission and application and funding rates from the previous fiscal year. So please I encourage you to check out our website, go through the CDMRP website as well there's other useful information there. And finally I got to point out before giving you a chance to ask some questions is we do have a webinar series that encapsulates some of what I've discussed today, about tips and tricks for applying to CDMRP funding opportunities.

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FY21 PRCRP Timeline

| ◆ Pre-proposal Mechanisms Deadlines | ◆ Letter of Intent Mechanisms Deadlines |
|---|--|
| <p>Idea Award and Impact Award</p> <ul style="list-style-type: none"> ◆ Pre-Application Submission Deadline: 5 pm ET, 20 May 2021 ◆ Invitation to Submit an Application: 8 July 2021 ◆ Application Submission Deadline: 11:59 pm ET, 8 September 2021 ◆ End of Application Verification Period: 5 pm ET, 15 September 2021 ◆ Peer Review: November 2021 ◆ Programmatic Review: February 2022 <p>◆ Pre-application → the preproposal 2 pages. ◆ The pre-proposal is reviewed! ◆ You need an invitation to submit!</p> | <p>Translational Team Science Award, Behavioral Health Science Award, and Career Development Award-Fellow</p> <ul style="list-style-type: none"> ◆ Pre-Application Submission Deadline: 5 pm ET, 29 July 2021 ◆ Application Submission Deadline: 11:59 pm ET, 18 August 2021 ◆ End of Application Verification Period: 5 pm ET, 25 August 2021 ◆ Peer Review: October 2021 ◆ Programmatic Review: December 2021 <p>◆ Pre-application → Letter of Intent ◆ A letter stating you intend to apply. It is NOT reviewed! ◆ You DO NOT need an invitation to submit!</p> |

26

So some of the information that I presented today would be reiterated in some of those webinars, but they again could be useful tools for you. So without any further ado I will open the floor up for questions.

Question and Answer

Stephanie Chisolm: Thank you so much Dr. Bunker this was wonderful and I hope a great resource for everybody that is listening, and remember that we will be posting a transcript as well as Dr. Bunker's slide and make all of those available to you. You'll also have access to the recording of today's program if you want to listen to it again. So we've had a couple of questions come in, of course can Impact Award have more than one PI?

Dr. Amie Bunker: They cannot have more than one named PI, you can have collaborators, you can have co-investigators that are listed in the budget but they would not be a named PI on the award, not like the translational team science.

Stephanie Chisolm: Mm-hmm (affirmative) Thank you. Okay, typically I'm sure you get a lot of proposals, what is the general percentage of proposals that make it through the programmatic review that eventually get funded?

Dr. Amie Bunker: So that varies, PRC is again a complex program. So what our programmatic panel tries to accomplish is make sure that we fund an appropriate number of... That's not the right way to say that. We want to make sure that we fund across all of our topic areas and then we also want to try to fund as much as we can across all of the different funding opportunities, but those are really going to depend on the number of applications that we receive. So some years we might have a huge number of bladder cancer applications, and maybe only a few mesothelioma. And so there's not one clear percentage that we're like, "Okay, across the board it's X percent of application."

So we have a lot of factors that we take into consideration and so that's why I mentioned the information paper. So in the information paper we break down how many applications we receive for each funding opportunity and how many were funded, and then also how many applications we received for each topic area and how many of those were funded. So I encourage people to go to the PRCRP website and you'll be able to see those numbers. Last I checked FY19 was still posted, but the FY20 numbers should be available soon.

Stephanie Chisolm: That was my next question. When are the fiscal year '20 awardees going to be announced and how will we find out how many people did apply for fiscal year '20?

Dr. Amie Bunker: So if you go to the PRCRP website... I just talked to Donna about this yesterday or the day before, and so she was working on it so it should be very soon. And anything that's listed on the website for FY20 they are currently... all the FY20 applications are still under the negotiation process. So there's a small chance that there might be... that list isn't 100% set yet, but it's going to be pretty accurate and not too much is going to change between now and when negotiations are finalized.

Stephanie Chisolm: Okay. One quick question and then I'm going to ask another bigger question. If somebody were to apply for one of your grants and in the meantime something else came through that funded a portion or most of what they were proposing to CDMRP, does that preclude them from accepting CDMRP funds or is that something they can expand their proposal once it's in, in some capacity to allow for that?

Dr. Amie Bunker: That's dealt with on a case by case basis. It really depends on how much overlap there is, in some cases maybe we could work with the investigator and say, "Okay, we'll remove this portion of the proposal and still fund this portion." But we don't really allow... we don't allow for changes to the core of the science because that's been peer reviewed, it went through programmatic reviews so that's what our panelists recommended for funding was a proposal as reviewed, and so we don't really allow too much changes. Like I said we'll try to salvage something if we can but we really encourage people that if they do submits... we know the funding levels, we know the challenges and it's not uncommon that similar or identical applications will be submitted to different locations. So it just might be something that if both are funded the investigator might just have to be prepared to choose one or the other.

Stephanie Chisolm: That's probably what happened in that negotiation period at the end, right? Decisions and commitments. Okay, great. And then I have one big question, can you clarify the difference between the idea and the Impact Awards?

Dr. Amie Bunker: Certainly. So just go back real quick. So the Idea Award... the main feature if you're going to remember one thing about the Idea Award innovation. What's new? We don't expect there to be preliminary data, it's a high risk high reward, it's a smaller... it's only 500,000 for three years. So really you're trying to collect some preliminary data to support a larger application for something like [RO1] or Impact Award. So we don't expect you to come to the table with much other than a well justified idea since idea work. The Impact Award and... Sorry, one other thing kind of on the flip side of that is, if something seems to develop as someone is submitting an Idea Award, and say they have a lot of data, and it sounds like a good idea but it's clearly just a continuation of ongoing research, that's a detriment to them actually because that's not meeting the intent of what we're looking for. So that's the main thing for an Idea Award versus the Impact Award, this is something where preliminary data is required. We are expecting this to be not high risk but have a high probability of success, so you just need... the investigator just needs the funding to work out the ideas, build up the infrastructure or build up the data to support say moving to a clinical trial.

That's really what we're trying to accomplish there is bridging that gap and moving an idea that will impact patients in the near term, moving that forward. And hence that's why it's a larger award, the 1.5 million over three years.

Stephanie Chisolm: Right. We have time for one last question, are there any different considerations if applying from an institution in Canada versus the United States as far as eligibility for programming?

Dr. Amie Bunker: No, we have several applications that are applicants who are from Canada and Spain and Australia-

Stephanie Chisolm: Okay, so you do accept international application?

Dr. Amie Bunker: We do.

Stephanie Chisolm: Okay, is clinical trials support allowed using the Idea Award?

Dr. Amie Bunker: No, it is not. So only the Impact Award, the Translational Team Science and the Behavioral Health Sciences can be used to support clinical trial costs, the Idea Award and the Career Development Award do not support clinical trial costs.

Stephanie Chisolm: Thank you. Well, Dr. Bunker I want to thank you so much. This has been a very informative hour, remember that we will be putting this recording up and you will have access to it very shortly, and also there is a court evaluation we'd love for you to give us your input on today's program, and we hope to see you Dr. Bunker next year.

Dr. Amie Bunker: Thank you for having me.