# The Congressionally Directed Medical Research Programs FY23 Overview

Presented by

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# **Vision and Mission**





# **Vision**

Transform health care through innovative and impactful research



# **Mission**

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

# **About CDMRP**





Started by Congress in 1992, CDMRP Manages Focused Biomedical Research

### **WHAT**

Funds Innovative and Impactful Biomedical Research

# **WHY**

Accelerating
Research to
Advance Cures,
Improvements, and
Breakthroughs

Transform
Healthcare
through
Innovative
and Impactful
Research



## WHERE

Research Conducted in Institutions Around the World

### HOW

Two-Tier Review
Process Involving
Scientists, Clinicians,
and Consumers

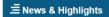




https://cdmrp.health.mil

# Background: Peer Reviewed Cancer Research Program





Department of Defense Peer Reviewed Cancer Research Program Funding Opportunities for Fiscal Year 2023 (FY23)

'Hard To Lose' Mutations In Tumors Predict Response To Immunotherapy (external link)

Novel CAR-T Therapy Targeting BAFF-R Against B-Cell Lymphomas

In Her Own Words: Melinda Bachini Speaks about Her Journey with a Rare Cancer and Her Experiences with Living Life to the Fullest

A Promising Nanotech Approach to Enhance Immunotherapy in Liver Cancer

#### Peer Reviewed Cancer



Vision – To advance mission readiness of U.S. military members affected by cancer and to improve quality of life by decreasing the burden of cancer on Service members, their families, Veterans, and the American public

Since Fiscal Year 2009, the Peer Reviewed Cancer Research Program (PRCRP) has been charged by U.S. Congress to fund innovative basic, applied, and translational cancer research to support Service members, their families, and the American public. Members of the military are exposed to hazardous environments due to the nature of their service and deployments and, thus, are at risk for the development of many types of cancers. The mission of the PRCRP is to successfully promote high-impact research for cancer prevention, detection, treatment, and survivorship. To accomplish this task, the PRCRP seeks to fund different areas of the research landscape. Funding innovative and translational research the PRCRP offers funding opportunities directed toward the special focus of Service members and potential cancer risks; focusing on the gaps in cancer research with respect to unique situations and military environments. Additionally, the PRCRP addresses growing and developing the future in research through targeted funding opportunities for early career investigators. With a funding program focused on military health and welfare in cancer research, the PRCRP strives to improve the quality of life by decreasing the impact of cancer on Service members, their families and the American public by funding highly relevant and innovative research

Peer Reviewed Cancer Research Program Overarching Challenges



» Click on Image to View Program Bookle



Began in Fiscal Year (FY) 2009 with an appropriation of \$16 Million (M) and congressional language directing the topic areas (specific cancers and other research areas) to be funded. From FY09-FY22, a total of 36 topic areas have been included under the PRCRP.

- FY09-FY22: \$784.8 M, 921 awards
- FY23: \$130 M, To be determined
- <u>Vision</u> To advance mission readiness of those U.S. military members affected by cancer; and to improve quality of life by decreasing the burden of cancer on Service Members, their families, Veterans, and the American public.
- •<u>Mission</u> To successfully promote high-impact cancer research for prevention, detection, treatment, quality of life, and survivorship.

cdmrp.health.mil/prcrp

# FY23 Topic Areas for Peer Reviewed Cancer Research Program



- Bladder Cancer
- Blood Cancer
- Brain Cancer
- Colorectal Cancer
- Endometrial Cancer
- Esophageal Cancer
- Germ Cell Cancers
- Head and Neck Cancer
- Liver Cancer
- Lymphoma
- Mesothelioma

- Metastatic Cancer
- Myeloma
- Neuroblastoma
- Pediatric, Adolescent and Young Adult Cancers
- Pediatric Brain Tumors
- Sarcoma
- Stomach Cancer
- Thyroid Cancer
- Von Hippel-Lindau
   Syndrome Malignancies
   (excluding cancers of the kidney and pancreas)

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

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



Research must be relevant to Service Members, their Families, Veterans, and other military beneficiaries

The inclusion of the individual Rare Cancers Research Program **shall not** prohibit the PRCRP from funding the above-mentioned cancers or cancer subtypes that may be rare by definition

# FY23 Congressional Language Relevance to Service Members and their families





### Impact of Cancer on Military Health



Traumatic brain injury increases hazard ratio for development of brain cancer

Environmental exposures such as asbestos leads to mesothelioma risk

Exposures to ionizing radiation leads to uterine, thyroid, blood, and other cancers

Infectious diseases such as H. pylori is associated with stomach cancer risk

Cancer diagnoses in Service Members and their families lead to force vulnerabilities

Gaps in our knowledge of cancer care cause gaps in mission readiness

Cancer affects the whole unit's readiness, not just a single Service Member

Military Health Systems are burdened with healthcare costs due to cancer diagnoses and treatment

### Requirement for all applicants to respond to **Military Health Focus Areas**

Military Health Focus	Required for All Applications	Programmatic Selection Factor	
Cancer Risk Factors	Environmental Exposures	Occupational Exposures	
Mission Readiness	Gaps in Research Spectrum	Gaps in Quality of Life	

# **FY23 PRCRP: Topic Areas and Portfolios**



**Stomach Cancer** 

malignancies

Neuroblastoma

General Oncology*	Hematology	Neurology	Otolaryngology	Pediatric	Reproductive Hereditary	Gastroenterology
Bladder Cancer Mesothelioma Metastatic Cancers	Blood Cancers Lymphoma Myeloma	Brain Cancer Pediatric Brain Tumors	Head and Neck Cancers	Pediatric, Adolescent and Young Adult Sarcoma Thyroid Cancer	Endometrial Cancer Germ Cell Cancers VHL	Esophageal Cancer Colorectal Cancer Liver cancer

<sup>\*</sup>Portfolio are not directed by Congress and are used for management purposes only. Other Portfolios such as Legacy Portfolios cover topic areas no longer included under PRCRP.

# FY23 PRCRP Cancer Capability Gaps Overarching Challenges



#### **Prevention**



- \*Develop innovative prevention strategies and early detection methods to decrease cancer burden
- \*Elucidate the mechanisms underlying cancer development to improve prevention methods

### **Diagnostics**



- \*Identify strategies to predict treatment resistance, recurrence, and the development of advanced disease.
- \*Distinguish unique features driving cancer occurrence across the spectrum of ages.
- \*Develop and improve minimally invasive methods to detect cancer initiation, progression, and recurrence

#### **Treatment**



- \*Transform cancer treatment, especially for advanced disease and metastasis
- \*Improve current therapies including systemic and local treatments.
- \*Longitudinal evaluation of disease progression and/or treatment response.
- \*Elucidate the mechanisms of cancer development to improve treatment methods

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# **FY23 PRCRP Cancer Capability Gaps Overarching Challenges - Continued**

### **Patient Well-Being and Survivorship**



- \*Develop strategies to address survivorship issues including quality of life, overall mental health, psychological impact of recurrence, and/or survivor permanent disability
- \*Develop strategies to reduce shortand long-term treatment effects, including neurocognitive deficits.
- \*Bridge gaps between treatment and survivorship including alternative medicine, nutrition and lifestyle factors, and supportive care

### **Disparity**



- \*Improve prevention strategies, diagnosis, treatment, and outcomes for patients in underserved or under recognized populations
- \*Develop strategies to improve accessibility to care and to address survivorship.
- \*Advance <u>health equity and</u> <u>reduce disparities</u> in cancer care through research.

#### Resources



- \*Develop open access platform(s) or methods/tools to coordinate and integrate multiple databases, biorepositories, and data-sharing interfaces
- \*Facilitate longitudinal collection of clinically annotated biospecimens and analysis of these specimens to further improve patient outcomes
- \*Develop technologies for machine learning and artificial intelligence to improve patient quality of life, survivorship, and outcomes

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# PRCRP: Esophageal Facts and Funding



### General Military Health Facts\*

- ◆VA allows Veterans to collect benefits for esophageal cancer due to Agent Orange and other related pesticides exposures.
- ◆Link to cancers such as esophageal cancer to contamination of water at Camp Lejeune
- ◆Esophageal cancer linked to exposures to various chemicals including trichloroethylene and tetrachloroethylene

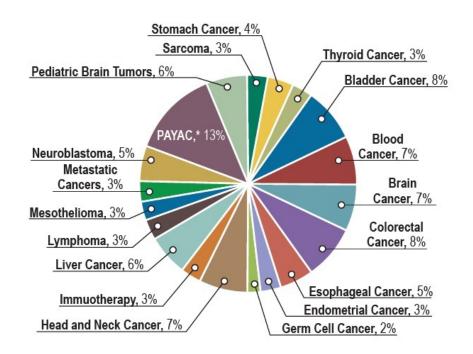
National Toxicology Program (NTP). Report on carcinogens. 14th edition. 2016. Mundt KA, Birk T, Burch MT. 2003. Int Arch Occup Environ Health. 76:473-91.

Paulu C, Aschengrau A, Ozonoff D. 1999. Environ Health Perspect 107(4):265-71

### Funding: FY20-FY22

Topic Area	#Awards	Investment
Esophageal Cancer	13	\$13.7M

### FY20-21 PRCRP Portfolio (% Research Dollars)



# PRCRP Strategic Plan Major Initiatives





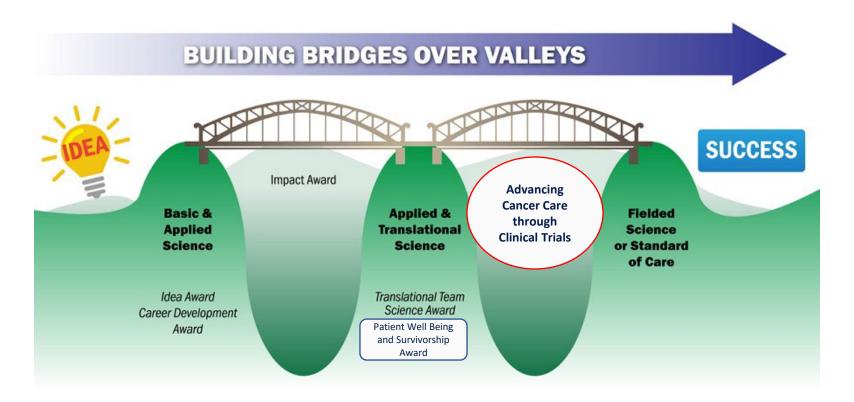
### Initiative I: Advance Convergent Science in Cancer Research

- Convergent Science Virtual Cancer Center to catalyze training of early career investigators in an interactive multi-cancer network.
- Cultivate convergent science to advance cancer research through innovative funding opportunities.
- Initiative II: Support the Research Continuum toward Fielded Science
  - Support innovative, discovery-based research.
  - Enhance translational research.
  - Accelerate research toward fielded science.

# Initiative II: Support the Research Spectrum FY23 Investment Strategy



- ✓ Choose the right funding opportunity
- ✓ Not all funding opportunities are alike



# **FY23 PRCRP Funding Opportunities**



		DEPARTMENT OF DEFENSE	
Mechanism	Key Characteristics	Funding (Direct Costs)	Deadline Dates
Advancing Cancer Care through Clinical Trials Award (ACCCT)	<ul> <li>Pre-application screened for invitation</li> <li>Supporting a clinical trial with focus on cancer care</li> <li>Preliminary data required</li> <li>Transition to next phase of development</li> </ul>	\$3M over 4 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Career Development Award- Fellow Option	<ul> <li>Letter of Intent: No invitation needed</li> <li>Eligibility: Research Assistant Professor, instructor.</li> <li>Early career investigators not fully independent.</li> <li>Intended to support the wider independence</li> </ul>	\$400K over 2 years	Letter of Intent (LOI): 25 July 2023 Full App: 10 Aug 2023
Career Development Award – Resident Option	<ul> <li>Letter of Intent: No invitation needed</li> <li>Eligibility: Physician Scientist in Residency.</li> <li>Research Funding levels for 1 year or 2 years</li> <li>Protected time required</li> </ul>	\$200K over 1 year \$400K over 2 years	LOI: 3 Aug 2023 Full App: 24 Aug 2023
Idea Award	<ul> <li>Pre-application screened for invitation</li> <li>High risk/high gain, innovation is key!</li> <li>Preliminary data discouraged</li> </ul>	\$400K over 2 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Impact Award	<ul> <li>Pre-application screened for invitation</li> <li>Supports research toward clinical applicability</li> <li>Clinical trials allowed</li> <li>Preliminary data required</li> </ul>	\$1M over 3 years	Preapp: 25 May 2023 Full App: 12 Sept 2023
Patient Well-Being and Survivorship Award	<ul> <li>Letter of Intent: No invitation needed</li> <li>Formerly Behavior Health Science Award</li> <li>Studies focusing on survivorship and Quality of Life</li> <li>Allows pilot clinical trials</li> </ul>	\$1M over 3 years	LOI: 25 July 2023 Full App: 10 Aug 2023
Translational Team Science Award	<ul> <li>Letter of Intent: No invitation needed</li> <li>Supports 2-3 Principal Investigators</li> <li>Correlative studies associated with a clinical trial</li> <li>Preliminary data required</li> </ul>	\$2.5M over 4 years	LOI: 25 July 2023 Full App: 10 Aug 2023

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# **Invitation Required Opportunities**



### Idea Award

- One-page pre-proposal
- Preliminary data is discouraged!
- Basic, high risk/high gain research
- Independent PIs
- \$400k over 2 years

### **Impact Award**

- One-page pre-proposal
- Clinical trial option
- Preliminary data is required
- Continuity of research with emphasis on near term impact
- Assistant Professor or equivalent
- \$1M over 3 years

# Advancing Cancer Care through Clinical Trials (ACCCTA)

- Three-page preproposal
- Pre-clinical data is required
- Clinical trial is required
- <u>No</u> preclinical projects allowed
- IND/IDE submission by time of application deadline
- Assistant Professor or equivalent
- \$3M over 4 years

Idea and Impact Awards: Pre-proposal due 25 May 2023 Invitation by 29 June 2023 Full application due 12 September 2023

ACCCTA: Pre-proposal due 25 May 2023 Invitation by 29 June 2023 Full application due 27 September 2023

# **Letter of Intent Opportunities**



# Patient Well-Being and Survivorship Award

- Letter of Intent: Pilot Clinical Trial (PCT) Option Preliminary data only required for PCT Option
- Independent Investigator
- Quality of life, preservation of function, neurocognitive issues, long term side effects
- \$1 M over 3 years

# Translational Team Science Award

- Letter of Intent: Clinical Trial Option
- Preliminary data required for supporting correlative studies associated with ongoing or completed clinical trial
- At least 2-3 PIs at the level of Assistant Professor
- \$2.5 M for 4 years

# Career Development Award –Fellow Option

- Letter of Intent: For scientists or Physician Scientists within 7 years of terminal degree
- Preliminary data not required
- Supports early career investigators toward further independence
- Research Assistant Professor, Instructor independent lab space is not required
- \$400k over 3 years

# Career Development Award – Resident Option

- Letter of Intent: For Residents to participate in research
- Preliminary data not required
- Supports two different research levels-required to perform work between June 2024-2026
- Research level 1: \$200K over 1 year or Research Level 2: \$400K over 2 years

Letter of Intent due 25 July 2023
Full application due 10 August 2023

# **Funding Opportunities**



- Pre-announcements and funding opportunity release notifications
  - CDMRP website and email blasts
- Funding opportunity postings
  - Grants.gov (CFDA 12.420)
  - CDMRP website (cdmrp.health.mil)
  - electronic Biomedical Research Application Portal (eBRAP) system (ebrap.org)
- Quickly find open CDMRP Funding Opportunities on the CDMRP website here:
  - Home > Funding Opportunities >
     Synopsis of Open Program
     Funding Opportunities



# **Applying for Funding**



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



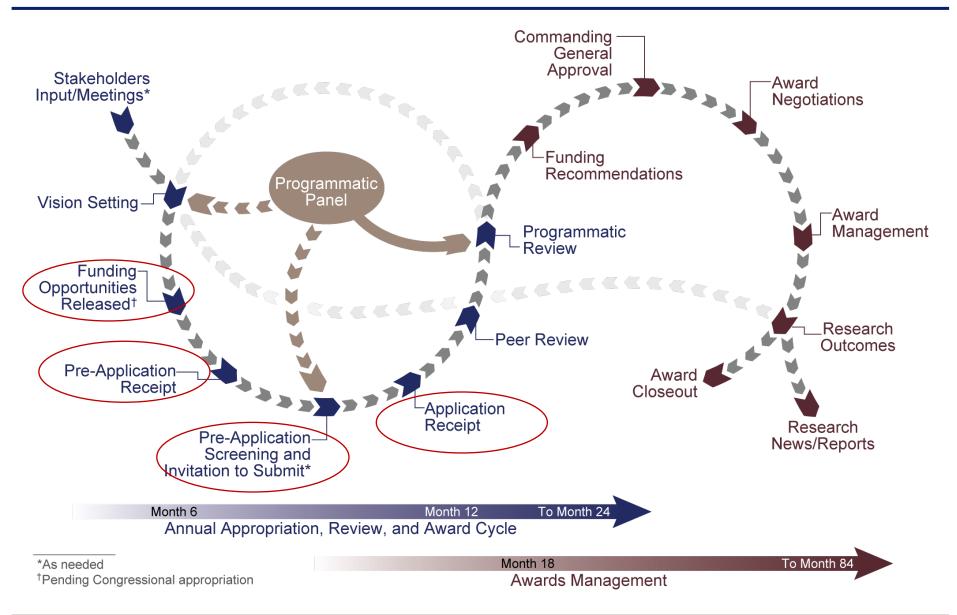
- The funding opportunity announcement contains information on:
  - Program Goals
  - Focus Areas/Topics
  - Award Intent
  - Required Elements, Eligibility, and Funding
  - Review Criteria
  - Deadlines

Single most important tip:

Read the announcement carefully

# **Program Cycle**





# 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 funding opportunity

### Peer Review

- Criterion-based evaluation of full proposal
- Determination of "absolute" scientific merit
- Outcome: Summary Statements
  - No standing panels; reviewers are recruited based on expertise needed
  - No contact between applicants, reviewers, and program staff

# **Partnership**



### Programmatic Review

- Comparison among proposals of high scientific merit
- Determination of adherence to intent, program relevance, and potential for impact
- Outcome: Funding Recommendations
  - No "pay line" (portfolio balance)
  - Funds obligated up-front;
     limited out-year budget
     commitments
     (but milestones imposed)
  - No continuation funding



Video and additional information available at: https://cdmrp.health.mil/about/2tierRevProcess

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# **Peer Review Criteria**



### (PRCRP verbiage example)

### II.E.1.a. Peer Review

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

Example Peer Review Criteria			
Scored		Unscored	
Principal Investion	gator	Personnel	
Career Development Plan, Environment, Career Guide		Budget	
Research Strategy and Feasibility		Application Presentation	
Impact	• Principal Investigator		
	Scored Principal Investig Career Developr Environment, Ca Research Strate	Scored  Principal Investigator  Career Development Plan, Environment, Career Guide  Research Strategy and Feasibility	



- Whether the PI meets the eligibility requirements.
- To what degree the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of cancer research.
- How relevant the research would be to support the early-career investigator toward wider independence and success.
- To what extent the PI's record of accomplishments and letters of support demonstrate
  their potential for advancement as a productive, independent investigator in cancer
  research in at least one of the FY23 PRCRP Topic Areas in <u>Section II.A.1</u> and at least
  one of the <u>FY23 PRCRP Overarching Challenges</u>.
- Whether the application demonstrates that the candidate has been named on and awarded nominal career development funding.

# **Programmatic Review Criteria**



### (PRCRP verbiage example)

#### II.E.1.b. Programmatic Review

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

- · Ratings and evaluations of the peer reviewers
- · Relevance to the mission of the DHP and FY23 PRCRP, as evidenced by the following:

### Fellow and Resident Options:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance to the FY23 Military Health Focus Areas
- Programmatic relevance to the FY23 PRCRP Overarching Challenges
- Relative impact

Programmatic Panel membership lists are available on the CDMRP website







Programmatic Panels

FY23 Programmatic
Panel

Previous Years'
Programmatic
Panels

## **Strategies to Answer Challenges**



### Plan Ahead

- **◆** Deadlines are important!
- **◆** Dissect the Funding Opportunity and Understand it
- ◆ Coordinate your efforts: bring the team together early

### Grantsmanship

- ◆ Clear voice, forget the jargon: don't tire the reviewers
- ◆ Review your documents prior to submission: use the verification period!
- ◆ Use the Peer Review Criteria as your check list!

### What's the Intent

- ◆ The Ted Talk: state your idea upfront, then back it up!
- Make your case to how your research aligns with the intent

Questions? help@eBRAP.org

### Impact

- ◆ Cool science is good: Impactful science is great!
- ◆ Show how it is impactful, important to patients
- ◆ Use plain language! You will be evaluated on this!

### Feasibility

- ◆ Clearly define your team's skills
- Outline your justification on how and why you can achieve the anticipated outcomes



### 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
- Do NOT ignore the Verification Period!
- Submit the correct Project Narrative and Budget
  - These components cannot be modified during the verification period in eBRAP

FY23 Panel Member				
Organization				
Lt. Col. Della Howell, M.D., U.S. Air Force Retired (Chair)				
Methodist Children's Hospital				
Jill Barnholtz-Sloan, Ph.D.				
National Cancer Institute				
Clark Chen, M.D., Ph.D.				
University of Minnesota				
Cmdr. Michele Gage, M.D., U.S. Navy				
Walter Reed National Military Medical Center				
Doug Hawkins, M.D.				
Seattle Children's Hospital				
Adam Hayden, (Consumer)				
National Brain Tumor Society				
Yin-Fen Lee, Ph.D.				
University of Rochester				
Barbara Lind (Consumer)				
Society of Gemological Oncology				
Aaron Mansfield, M.D.				
The Mayo Clinic				
Robert Mesloh (Consumer)				
Lymphoma Research Foundatio				
Col. Thomas Newton, M.D., U.S. Air Force Retired				
Inova Schar Cancer Institute				
Col. Aaron Pitney, M.D., U.S. Army				
U. S. Army Training and Doctrine Command				
Heath Skinner, M.D., Ph.D.				

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University of Pittsburgh Kenneth Tanabe, M.D.

Massachusetts General Hospital

# **FY23 PRCRP Funding Opportunities**



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Mechanism	Key Characteristics	Deadline Dates
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Idea Award	<ul> <li>Pre-application screened for invitation</li> <li>\$400 over 2 years</li> </ul>	Preapp: 25 May 2023 Full App: 12 Sept 2023
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Translational Team Science Award	<ul> <li>Letter of Intent: No invitation needed</li> <li>\$2.5M over 4 Years</li> </ul>	LOI: 25 July 2023 Full App: 10 Aug 2023

# Questions? For more information, please visit:



