New York State Department of Health
Prostate and Testicular Cancer Research and Education Fund

2021 Report

Background

The New York State Prostate and Testicular Cancer Research and Education Fund (the Fund) was created as a result of an amendment to State Finance Law (SFL) §95-e, enacted as part of the 2014-15 State budget. The law authorized the Commissioner of Health to provide grants for the purpose of advancing and financing prostate and testicular cancer research, support programs and education projects, using the revenues received as part of the Fund. Available funding to support this initiative is limited to the amount(s) appropriated in the enacted State Fiscal Year budgets and as set by the New York State Division of Budget.

State Finance Law requires the Commissioner of Health to provide an annual report describing how monies from the fund were used in the prior calendar year. The following is a description of activities conducted in 2021 to issue contracts to new grantees awarded through a Solicitation of Interest issued in 2019.

Solicitation of Interest (SOI) and Awards for Prostate Cancer Research Grants for National Cancer Institute (NCI)-Designated Cancer Centers Located in New York State (NYS)

In January 2020, the Department of Health (the Department) awarded grants to six National Cancer Institute (NCI)-designated Cancer Centers that responded to a Solicitation of Interest (SOI) released in 2019. The intent of the SOI was to maximize the potential impact and reach of the funding to advance research into prostate cancer to address its heavy burden on New Yorkers, in particular those New Yorkers disproportionately impacted by this disease. The noncompetitive procurement sought to make awards in sufficient amounts to NYS institutions with experienced principal investigators and infrastructure to meet the intent of the grant funding. The SOI funding also intended to establish the basis for pursuing additional funding opportunities through other entities such as the National Institutes for Health/National Cancer Institute or the Department of Defense. Awardees will make research grants through their internal peer review processes to investigators at or above the level of postdoctoral fellow (or equivalent) to conduct innovative, hypothesis-developing research that is either determined to be no greater than minimal risk, exempt under 32 CFR 219.101(b) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110 by the local Institutional Review Board (IRB) of record.

Contracts with the six grantees were to begin June 1, 2020 for the two-year period ending May 31, 2022. At the direction of the Department, the contracts were delayed by one year, due to the COVID-19 pandemic. In March 2021, the Department initiated contract development activities with the six grantees, executing contracts each at $173,333 for the two-year period beginning June 1, 2021 and ending May 31, 2023. Bureau of Cancer

Prevention and Control and Division of Chronic Disease Prevention staff conducted a webinar for grantees to review the contracting process and offered technical assistance to ensure timely contract execution.

Grantees

1. Cold Spring Harbor Laboratory Cancer Center, Cold Spring Harbor, NY
2. Herbert Irving Comprehensive Cancer Center, Trustees of Columbia University in the City of New York, Manhattan, NY
3. Laura and Isaac Perlmutter Cancer Center at NYU Langone Health, Manhattan, NY
4. Roswell Park Comprehensive Cancer Center, Buffalo, NY
5. The Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, Manhattan, NY
6. Memorial Sloan-Kettering Cancer Center, Manhattan, NY

Work Plans

Contract work plans require that grantees:

1. Solicit research proposals that meet the SOI criteria,
2. Acquire peer review and select research projects/s and investigators that meet the funding criteria,
3. Engage investigators and initiate and monitor progress on selected research projects, and
4. Conduct administrative and fiscal oversight to ensure completion of all required contract activities.

2021 Activities

The majority of the grantees spent the first three to six months of the contract, from June through December 2021, developing competitive requests for research applications, soliciting, reviewing and awarding research applications, and acquiring approvals to conduct the research through Institutional Review Boards (IRB) or other appropriate governing, peer review bodies. For the period June 1, 2021 to December 31, 2021, grantee activities were the following:

Cold Spring Harbor Laboratory Cancer Center – The grantee issued an internal, competitive request for research applications, conducted a peer review of the applications, selected one application for funding, and acquired IRB approval for the research. The selected research project is titled, "*New Tumor Suppressor Genes on Chromosome 10*" and the principal investigator (PI) is Lloyd C Trotman, PhD. The innovative hypotheses being tested are: 1) there is a yet undiscovered tumor suppressor on chromosome 10 that intersects with the PTEN gene to increase the likelihood of prostate cancer recurrence, and 2) endocytosis plays a role in prostate cancer biology.

Herbert Irving Comprehensive Cancer Center, Trustees of Columbia University in the City of New York – The grantee released a competitive request for research applications, conducted an administrative review of all applications, and assigned each application to two to three scientific reviewers who are members of the institution's Pilot Grant Committee. The Pilot Grant Committee made a recommendation for funding one research project titled, "*The*

influence of radiotherapy on the regenerative balance of T-cells to overcome therapy resistance and improve outcomes for patient's prostate cancer"; Catherine Spina, MD, PhD, is the PI. The research received IRB approval. The innovative hypothesis is to study the influence of radiotherapy on the regenerative balance of T-cells.

Laura and Isaac Perlmutter Cancer Center at New York University Langone Health – The grantee formed an internal application review committee, developed and distributed a competitive request for research applications, completed application reviews, and awarded two research projects:

1) "*Lifestyle Modification in Patients with Prostate Cancer*"; Stacy Loeb, MD, is the PI. This innovative hypothesis examines an intervention to improve sleep health for patients with prostate cancer and their caregivers. The research received IRB approval.
2) "*Activitation of anti-tumor immunity in prostate cancer by an AR-targeting peptoid conjugate*"; Michael Garabedian, PhD, is the PI. The innovative hypothesis is that treating castration-resistant prostate cancer (CRPC) tumors with MPC309 gives the ability to evoke innate immune cell infiltration into the tumor, and therefore could potentiate a cytotoxic T-cell response and bolster the therapeutic efficacy of immune checkpoint blockade (ICB) antibodies. Given the higher incidence of CRPC in black men, successful fulfillment of the study aims could have a greater impact on prostate cancer treatment among black men. The research received Institutional Animal Care and Use Committee (IACUC) approval.

Roswell Park Comprehensive Cancer Center – The grantee issued a competitive request for proposals, broadly distributed to the cancer center faculty, and received six applications in response. An application committee reviewed and recommended three applications for funding and submitted them to the internal Office of Research Subject Protection. All three projects were approved in December 2021:

1) "*Tumor Suppressive Functions of SIRT3 in Prostate Cancer Progression*"; Subhamay Dasgupta, PhD, is the PI. The innovative hypothesis seeks to define the tumor suppressive functions of SIRT3 in lethal prostate cancer pregression. The research was determined by the IRB to be exempt under 32 CRF 219.101(b).
2) "*Development of Prostate Specific NCOR2 Knockout Mouse*"; Dominic Smiraglia, PhD, is the PI. This innovative hypothesis seeks to develop a new mouse model with targeted knockout of NCOR2 in the context of PTEN loss. The research was determined by the IRB to be exempt under 32 CRF 219.101 (b).
3) "*Advanced Prostate Cancer Database: single-cell analysis/digital spatial profiling*"; Gurkamal Chatta, MD, PI. The research goal is to annotate clinical specimens and integrate two databases to better understand mechanisms of response/resistance in advanced prostate cancer at a clinal and molecular level.

The Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai – An oversight committee developed and issued a competitive request for research proposals in June, but received no applications. The request was re-issued in November and 11 applications were received by the December deadline. Applications will be reviewed and awards made in January 2022.

Memorial Sloan-Kettering Cancer Center – The grantee was unresponsive to multiple requests for expense and progress reports and was issued a corrective action letter in December 2021 which set deadlines for delinquent contract deliverables. Department program and contract managers will track the corrective action through March 2022; lack of response may result in contract termination.

Summary Financial Plan

Cash Disbursement Summary

Cash Revenue in Account Start of SFY 20-21	$2,919,145
Disbursements SFY 20-21	$0
Cash Revenue in Account Start of SFY 21-22	$3,154,137
Actual Disbursements SFY 21-22	$57,854.36
Cash Revenue in Account as of 4/1/22	$3,288,851

Projections SFY 20- 23	**2019-20**	**2020-21**	**2021-22**	**2022-23**	**2023-24**	**2024-25**
Beginning Balance	$2,585,246	$2,919,145	$3,154,137	$3,288,851	$3,068,851	TBD
Receipts*	$333,899	$234,992	$192,568	$300,000	$300,000	$300,000
Disbursements	$0	$0	($57,854)	**($520,000)	TBD	TBD
Ending Balance	**$2,919,145**	**$3,154,137**	**$3,288,851**	**$3,068,851**	**TBD**	**TBD**

*SFY 22 - 25: the estimated revenues are based on prior years.
** Projected disbursements SFY 22-23

Expenditure Notes:
While there is $3,154,137 in the Fund balance, the Fund received an appropriation of $840,000 in the 2021-2022 State Fiscal Year. Budgeted expenditures for the grantees are based on the cash ceiling set by the Division of Budget at $520,000 for SFY 2022-2023.

Grantee contracts were delayed by one year due to the COVID-19 pandemic and began June 1, 2021; therefore, there are no expected expenditures from January 1 to May 31, 2021. The Grantees' work in the first quarter of their two-year contract period, June 1 to December 31, 2021, focused on developing, issuing, reviewing applications, making awards for research, and facilitating required peer, institutional research reviews. Research projects primarily will begin in January 2022 and will be conducted through the end of the contract period, May 31, 2023. Therefore, there were few expenditures through December 31, 2021 but an increase in expenditures is anticipated beginning January 2022 as most research projects are underway. The potential termination of one grantee due to unresponsiveness to contract requirements may further reduce planned expenditures.