

LFIR # 2082

1. Project Title	Initiation of pivotal research program on COVID-19 and development of a Transplant BioBank
	I ransplant BioBank

2. Senate Sponsor Danny Burgess

3. Date of Request 03/19/2021

4. Project/Program Description

To provide funding to study the COVID 19 immune and clinical response in organ transplant recipients and to develop a biorepository that will collect, process, store and distribute biospecimens from transplant recipients for future scientific investigation within the Tampa General Hospital Transplant Institute. This biorepository will guide the development of future diagnostic and therapeutic regimens against novel diseases and infections that may affect the highly vulnerable transplant population.

5. State Agency to receive requested funds	
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Department of Health

State Agency contacted? Yes

6. Amount of the Nonrecurring Request for Fiscal Year 2021-2022

Type of Funding	Amount
Operations	1,000,000
Fixed Capital Outlay	0
Total State Funds Requested	1,000,000

7. Total Project Cost for Fiscal Year 2021-2022 (including matching funds available for this project)

Type of Funding	Amount	Percentage	
Total State Funds Requested (from question #6)	1,000,000	98%	
Matching Funds			
Federal	0	0%	
State (excluding the amount of this request)	0	0%	
Local	0	0%	
Other	25,000	2%	
Total Project Costs for Fiscal Year 2021-2022	1,025,000	100%	

8. Has this project previously received state funding? No

Fiscal Year	Amount		Specific	Vetoed	
(уууу-уу)	Recurring	Nonrecurring	Appropriation #		

9. Is future funding likely to be requested?

No

a. If yes, indicate nonrecurring amount per year.

b. Describe the source of funding that can be used in lieu of state funding.

10. Has the entity requesting this project received any federal assistance related to the COVID-19 pandemic?

Yes



If yes, indicate the amount of funds received and what the funds were used for.

Tampa General Hospital received approximately \$51.6 million which was ALL used to mitigate additional expenses and lost revenue attributable to the COVID-19 pandemic.

11. Details on how the requested state funds will be expended

Spending Category	ing Category Description		
Administrative Costs:			
Executive Director/Project Head Salary and Benefits	Support for Principle investigator and sub- principle investigator.	200,000	
Other Salary and Benefits	Salary support for research coordinators	200,000	
Expense/Equipment/Travel/Supplies/ Other	Facility support	100,000	
Consultants/Contracted Services/Study		0	
Operational Costs: Other			
Salary and Benefits	Salary support to perform case collection (tissue acquisition, pathology/histology review, informed consent documentation, case data collection, preparation of collection kits and tissue processing (Tissue Processing: data annotation, confirmation of diagnosis, detailed pathology work-up, including digital imaging and image analysis, molecular analysis and genetic marker tests.)	200,000	
Expense/Equipment/Travel/Supplies/ Other	equipment/Travel/Supplies/ Purchase of equipment to hold the inventory of physical biospecimens (eg. freezers, racks, collection and storage supplies)		
Consultants/Contracted Services/Study		0	
Fixed Capital Construction/Majo	r Renovation:		
Construction/Renovation/Land/ Planning Engineering		0	
Total State Funds Requested (m	ust equal total from question #6)	1,000,000	

12. Program Performance

a. What specific purpose or goal will be achieved by the funds requested?

The short term goal of this project is to understand how COVID-19 affects transplant recipients and learn the effect of the COVID vaccinations in this patient population. The longer term objective is to prospectively develop a repository of biospecimens which will help in future development of diagnostics, treatment and preventative strategies against novel diseases and infections that may affect the highly vulnerable transplant population.

b. What activities and services will be provided to meet the intended purpose of these funds?

Immediately, we will initiate a research study (that is already IRB approved) that will enroll all liver, kidney, pancreas, heart and lung transplant patients at Tampa General Hospital (TGH). Blood samples will be collected at the time of vaccination and 1, 2, 3, 4 weeks and then at 3 month, 6 month, 9 month and 1 year. For patients who receive the vaccine pre-transplant, samples will be collected at 1, 3, 6, 9, 12 months post-transplant. These will be compared to non-transplant patients vaccinated at our institution as part of the Global Emerging Disease Institute at Tampa General Hospital. The primary goal to understand the antibodies developed in immunosuppressed patients. Peripheral blood cells (PBC) and serum will be isolated and stored for future scientific studies. All of these samples will be stored in freezers and saved for long term use for future research studies. This will be the inception of a transplant BioBank.

c. What direct services will be provided to citizens by the appropriation project?



The project will study how transplant patients respond to the COVID-19 vaccine and the COVID-19 virus. Immunological responses will be determined at various time points either after vaccination, infection or transplant and correlated with clinical severity of disease and transplant organ function and outcome. The biorespository will be used to test any future individualized diagnostic tests or therapy towards not only COVID-19 virus and the emerging viral strains/variants, but also against future viral diseases that can impact vulnerable immunosuppressed transplant patients.

d. Who is the target population served by this project? How many individuals are expected to be served?

There are currently over 1,100 patients awaiting organ transplant at Tampa General Hospital and over 11,000 patients who have received organ transplants. There are approximately 5,300 patients awaiting organ transplants in Florida. All of these patients will directly or indirectly benefit from this project.

Tampa General is home to the #6 organ transplant center in the United States.

e. What is the expected benefit or outcome of this project? What is the methodology by which this outcome will

be measured?

The results from this study will facilitate the development of vaccination, prophylaxis and treatment guidelines for organ transplant recipients against COVID-19. As more viral variants of the COVID-19 virus are being detected, samples collected as a part of this study will be used to develop a bio-repository to study the effect of the newer viral variants and other infections on post transplant immune function and graft outcomes. This will help in the development of targeted diagnostic testing, and individualized treatment options to protect vulnerable transplant patients against new viral diseases and improve long term outcomes. We will test blood and nasal swab samples for various virus specific immune responses, and also detect for viral variants and new viruses using next generation genetic testing.

f. What are the suggested penalties that the contracting agency may consider in addition to its standard penalties for failing to meet deliverables or performance measures provided for the contract?

Standard Penalties

13. The owners of the facility to receive, directly or indirectly, any fixed capital outlay funding. Include the relationship between the owners of the facility and the entity.

The owner of the facility is the entity, Tampa General Hospital.



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14. Requestor Contact Information

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15.							
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	c. Organization Ty	ре					
	□For Profit Entity	ofit Entity					
	☑Non Profit 501(c	:)(3)					
	□Non Profit 501(c	c)(4)					
	□Local Entity						
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	□Other (please sp	pecify)					
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