

4300 N. Lamar Blvd., Austin, TX 78756 | WeAreBlood.org

COVID-19 Convalescent Plasma (CCP) Program Funding Proposal for Williamson County

November 2020

Background

On April 4, We Are Blood (WrB) became one of the first blood centers in the country to stand up a program to collect COVID-19 Convalescent Plasma (CCP) for distribution to local physicians to administer under the Mayo Clinic's Expanded Access Protocol (EAP) approved by the FDA for Investigational CCP. The CCP Program has distributed more than 1600 doses of CCP for local COVID-19 patients.

Transition to Emergency Use Authorization (EUA)

In late August, the FDA announced its new Emergency Use Authorization (EUA), further expanding access to CCP beyond what was allowed under the investigational EAP. The EUA also adds the requirement that all CCP be labeled as either "high titer" or "low titer" which imposes new testing requirements to measure antibody titer levels.

A New Need for Program Stability and Funding

The new antibody testing requirement adds a significant cost for which We Are Blood must secure funding in order to keep this vital program alive.

Starting in April, the CCP Program built processes for recruiting donors and for collecting and distributing CCP. It steadily kept supply ahead of demand and built a comfortable inventory based on hospitalization rates and CCP usage.

Then suddenly in July, cases and hospitalizations surged, resulting in a spike in demand that quickly depleted CCP inventory. Clinicians had to adjust treatments to less than optimal doses, and WrB had to import CCP just to keep up.

New public orders then resulted in another decline and stabilization in cases and hospitalizations. WrB had weathered the July storm and built back a comfortable inventory – for now.

But to maintain stability going forward and shield against these inevitable swings and uncertainties, the CCP Program needs new funding to secure its operation for the next 12 months.

WrB needs to recruit and maximize donations from recovered COVID-19 patients. It needs to build a long-term inventory that can meet any demand (sudden or routine) for optimal CCP therapy until the course of this pandemic ultimately reaches its end.

The funding plan to ensure program viability for the next 12 months thus includes two components: Antibody Testing, and Expanding Capacity.

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Funding Request

The entire budget for the CCP program outlined above is \$351,950. We Are Blood has requested partner funding for this program from Travis County and is allocating funding from a recent grant from Union Pacific Foundation. Among the 10 counties We Are Blood serves, we are seeking funding primarily from Travis County and Williamson County, as they are the counties treating the majority of COVID 19 patient s in Central Texas and ordering 96% of CCP units (see We Are Blood CCP Distribution Table below).

We are request that **Williamson County** consider funding **\$63,351** of this budget to ensure we have adequate CCP in our Central Texas community to treat COVID-19 patients during the ongoing pandemic.

CCP Partner Funding Breakdown

Funder	Amount	Status
Travis County	\$274,521	Pending vote
Williamson County	\$63,351	In discussion
Union Pacific Foundation	\$14,078	Awarded
Total	\$351,950	

CCP Proposal Detailed Budget

Antibody Testing

This 12-month program will allow WrB to screen all blood donors for positive antibodies to identify those who might be eligible for CCP donation, and then to perform titer testing on those whose screen is antibody positive (estimated 3%). This includes titer testing on existing CCP inventory to meet EUA requirements by the Dec 1 transition deadline.

Estimated 51,110 antibody screening tests @ \$4.50	\$229,950
Estimated 4,000 antibody titer tests @ \$17.50	<u>70,000</u>
Total Antibody Testing – 12 months	\$299,950

Expanded Capacity

Currently, CCP collection is limited to Trima technology at our fixed-site donor centers. Purchasing two Alyx technology collection machines will enable CCP collection on mobile buses for expanded capacity and flexibility.

Alyx Apheresis collection machines (2) \$52,000

Total Program Funding Proposal \$351,950

We Are Blood CCP Distribution Table

252 Williamson County patients have received CCP therapy from units distributed by We Are Blood of a total 1,300 patients across Central Texas who have received CCP therapy. When our inventory is adequate, physicians typically order two units per patient. During the height of the spike in cases in Central Texas over the summer, we had to limit order fulfillment to one unit per patient. Below is a breakdown of CCP units distributed by We Are Blood by county.

County	Facility Name	2020 CCP Units Shipped	Percent of Total Distribution		
Travis	ASCENSION SETON MC	408	26%		
	BSW MC AUSTIN	13	1%		
	BSW MC LAKEWAY	20	1%		
	BSW MC PFLUGERVILLE	48	3%	78%	
	DELL CHILDREN'S	3	0%		
	DELL SETON MC AT UT	330	21%		
	NO AUSTIN MED CTR	71	4%		
	SO AUSTIN MED CTR	284	18%		
	ST DAVIDS MED CTR	53	3%		
Hays	BSW MC BUDA	16	1%	3%	
	CHSR - SAN MARCOS	36	2%		
Burnet	BSW MC MARBLE FALLS	14	1%	1%	
Williamson	BSW MC ROUND ROCK	51	3%		
	BSW MC TAYLOR	8	1%		
	CEDAR PARK MED CNTR	43	3%	18%	
	ROUND ROCK HOSPITAL	114	7%		
	ST DAVIDS- GEORGETOWN	73	5%		