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## The CTSA University of Texas Health Science Center (UTHSC) Northeast—Tyler and Rio Grande Valley Success Story: How Rural, Underserved Academic Communities Rapidly Built a Robust Engine for Collaborative COVID-19 Clinical Research

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## The CTSA University of Texas Health Science Center (UTHSC) Northeast—Tyler and Rio Grande Valley Success Story: How Rural, Underserved Academic Communities Rapidly Built a Robust Engine for Collaborative COVID-19 Clinical Research

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### Summary:

In 2018, The University of Texas Health Science Center–Tyler and University of Texas Rio Grande Valley were invited to develop clinical research units for an existing Clinical and Translational Science Award (CTSA) consortium with the objective to equip medically underserved, economically disadvantaged communities and subsequently to deploy COVID-19 clinical trials in response to a public health emergency.

### Keywords

COVID-19; clinical trial; clinical research unit; convalescent plasma; rural health care; community outreach; medically underserved communities; public health

### Background

Established in 2011, the National Center for Advancing Translational Science (NCATS) is one of 27 institutions constituting the U.S. National Institutes of Health (NIH). Its mandate is to “understand—and thereby improve—translation, which is the process through which new interventions that improve human health are developed and implemented.”<sup>1</sup>[p.5] To this end, NCATS provides Clinical and Translational Science Awards (CTSAs) to foster more multi-disciplinary collaborative research focused on addressing community needs and building a translational science workforce. Dr. Elias Zerhouni initiated these awards in 2006 to replace legacy grants supporting general clinical research centers. As of 2019, there

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were approximately 60 CTSA (Hubs) in the country,<sup>2</sup> including the Center for Clinical and Translational Sciences (CCTS) in Houston, Texas, which was established in 2006, along with others, to integrate special populations into the full spectrum of clinical and translational research, and to streamline such research through institutional review board (IRB) reciprocity, data warehouses, biobanks, and other innovations. The CCTS catchment area serves 13.5 million residents including 37.4% Hispanic in Houston, 91.7% Hispanic in the Rio Grande Valley, and 15.2% Hispanic and 15.6% Black in Tyler, with an average poverty rate of 21.2% across the three regions (Figure 1).

In early 2018, we in Houston invited the University of Texas Health Science Center–Tyler (UTHSC-Tyler) and The University of Texas Rio Grande Valley (UTRGV) to join the CCTS as Clinical Research Units (CRUs). The term *CRU* is used expressly by NCATS and CTSA to denote a physical space dedicated to translational research that is collaborative, provides a platform for workforce development, and operates clinical trials that translate research to the community. The objective was to equip rural, medically underserved, and economically disadvantaged communities such as Tyler in northeast Texas, El Paso in the west, and the Rio Grande Valley in the south, to conduct collaborative research (Figure 1). Prior to the pandemic, UTHSC-Tyler faculty members were also engaged in multiple community-based initiatives aimed at improving population health by providing community health worker training, especially in rural settings. The school also serves seven rural counties in the NIH Rapid Acceleration of Diagnostics for Underserved Populations (RADx-Up) program in order to improve access to COVID testing and identify COVID disease “hot spots.” Acting as a COVID vaccine hub, UTHSC-Tyler has provided over 55,000 vaccinations to many rural residents. The Nurse Family Partnership program provides home visiting nurses for first time expectant mothers. Moreover, faculty members engage closely with local health departments, serving as the local health authority for Smith County, Texas.

These groups were poised to respond to the COVID-19 disaster, which began to unfold in March 2020. The pandemic has acutely and disproportionately affected rural communities that were already facing severe disadvantage in medical services and infrastructure,<sup>3</sup> such as those situated in east and southwestern Texas. As of April 7, 2021, the state of Texas has reported more than 2,400,000 COVID-19 cases with more than 47,000 fatalities.<sup>4</sup> COVID-19 has prompted a historic, rapid-fire launch of clinical trials of vaccines and possible treatments, including administration of plasma from recovering COVID-19 patients. Indeed, the NIH has expressly capitalized on existing CTSA hubs as launch pads for such trials. This approach, repurposing existing resources to meet large-scale, unique, emergent public health needs to combat COVID-19, has been successful in other cases. At UTHSC Tyler, a new nurse coordinator was hired for the clinical research team to provide additional support for the new COVID-19 clinical trials. To enable rapid responses for in-patient recruitment and other trial needs, the entire research team was relocated to an entire floor of a building proximate to the main campus hospital. An office and examination room were dedicated to the CCTS CRU at that location. In April of 2021, a new COVID-19 clinic with three additional examination rooms was established in the pulmonary clinic area on the UTHSC-Tyler North campus. The UTHSC-Houston site re deployed two full-time physicians and two study coordinators and hired five new study coordinators, a laboratory technician, and two research nurses. They repurposed space unoccupied by staff working at

home for the new team. The same approach was used to rapidly train health care providers in telehealth using the National Geriatric Network<sup>5</sup> and to surveil COVID-19 in rural South Africa.<sup>6</sup>

The University of Texas Health Science Center–Tyler has now deployed CCTS support to maximum effect, launching clinical trials of convalescent plasma (CONTAIN)<sup>7</sup> against COVID-19 as cases surged in surrounding East Texas communities. The University of Texas Health Science Center–Tyler has since become one of the largest enrollment centers into this nationwide trial, and nearly reached its yearly trial enrollment goal of 100 participants in six months, with launch at Tyler in late August 2020 and 96 participants (28% Black) enrolled by February 2021 (Table 1). The UTHSC-Houston site, launched at the same time, enrolled 146 participants. The trial ceased enrollment in March 2021, with 246 participants enrolled across the three sites with 15% Black, 56% Hispanic, and 29% White (non-Hispanic) (Table 1).

This trial was initiated in the U.S. in April 2020 to assess, in the absence of other proven interventions at that time, whether in-patients with moderate to severe disease benefit from convalescent plasma. Data have since shown that convalescent plasma may be less effective than originally hoped, except to prevent severe disease in older adults with mild symptoms.<sup>8,9</sup> The University of Texas Health Science Center–Tyler will also open four other COVID-19 projects following the same CCTS framework (Box 1). The University of Texas Health Science Center–Tyler’s success demonstrates that given the right mandate, funding, and infrastructure including strong CTSA-level support, small, rural underserved communities can respond to public health emergencies. A similar approach was also used by communities in Arkansas to ensure sustainable collection and equitable delivery of COVID-19 convalescent plasma,<sup>10</sup> but we had the additional challenge of reaching populations across the majority of the vast geographical state of Texas encompassing 268,596 square miles.<sup>11</sup> The UTHSC-Tyler’s success also highlights the benefits derived by medically underserved communities from CTSA and similar initiatives (e.g., the proposed community health observing system for the Gulf of Mexico region).<sup>12</sup> Finally, UTHSC-Tyler’s experience demonstrates that important clinical trials can flourish even in adversity, and even in communities that are not historically accustomed to or are distrustful of medical research due to unethical historical and social circumstances, beginning with the use of slaves and free Black people in medical experiments and including the U.S. Public Health Service Study of Untreated Syphilis in the Negro Male at Tuskegee (often called the *Tuskegee Syphilis Study*).<sup>13</sup>

Trade-offs occurred due to the singular focus on COVID-19 clinical research, which included decisions to table other non-COVID-19 research; reallocation of these resources meant shifting away temporarily from other previously highly prioritized research including non-medical opioid use research. Our CTSA also had a summit planned for diabetes and obesity research development, which was tabled to give full attention to the exigency of the NIH COVID-19 trials to which we had committed.

## The Houston CCTS in Brief

The CCTS, having been one of the first CTSAAs to be awarded, has become a center for clinical and translational research for east and south Texas and nationally. It was initially established as a partnership between The University of Texas Health Science Center–Houston and The University of Texas MD Anderson Cancer Center, but it has since grown to a consortium that now includes Rice University in Houston, UTHSC-Tyler, and UTRGV. With a view to helping improve individual and public health in the region and in the nation, the CCTS has endeavored since its inception to expand the translational science workforce, lower research barriers, and streamline research through IRB reciprocity. It also supports biobanks and data warehouses; integrates pediatric, elderly, Hispanic, and LGBTQ+ populations into clinical and translational research; encourages collaboration across disciplines; and supports neighboring institutions that lack CTSAAs. The catchment area now encompasses about 23,000 square miles with a population of 13,500,000 (4% of the U.S. population) and some of the greatest diversity in the country. Houston is the 4th largest and most ethnically diverse city in the U.S. and is 45% Hispanic, 23% African American, 7% Asian, 11% elderly, and 20% economically challenged; while northeast Texas is about 16% African American, 15% Hispanic, 18% elderly, and 16% economically challenged; and the Rio Grande Valley in South Texas is about 16% elderly and 30% economically challenged.<sup>14</sup> South Texas is 97% Hispanic and is home to 15.5% (4.5 million) of the state’s population of 29 million. South Texas residents struggle with lower educational levels, less income, and less access to health care than the rest of the state. This places them in greater danger of facing dire health problems such as obesity or cancer. To date, the CCTS has provided services to 1,771 investigators and 3,970 projects, generating more than 3,150 publications in journals with an average impact factor of 6.2. The health challenges of the populations served by the CCTS at UTHSC-Tyler, UTRGV, and UT Houston are shown in Figure 1.

## Community Outreach for COVID-19-related Clinical Research in Northeast Texas via UTHSC-Tyler and in Southwest Texas via UTRGV

The CCTS recruited UTHSC-Tyler in order to expand its reach into rural, medically underserved east Texas communities. The Tyler and surrounding rural population is characterized by high use of tobacco, incidence of lung cancer, alcoholism, suicide, and other health issues associated with rural communities.<sup>15</sup> The goal was to build and fund a CRU that would bring together UTHSC-Tyler and community doctors to serve approximately 1.3 million Texans and that could respond to the current pandemic (Figure 1).

Although the push to recruit UTHSC-Tyler was initially predicated on the goal to extend the diversity and geographic reach of the CCTS, the presence there of an interested and accomplished pulmonary research team provided further impetus. The University of Texas Health Science Center–Tyler has built an internationally recognized program on lung injury and repair and pulmonary infectious diseases, the signature areas of its institutional research enterprise. Faculty in the pulmonary division have considerable expertise in the conduct of clinical trials in various lung diseases, although all other departments are relatively

less experienced. The University also operates an experienced clinical research office that provides study management, financial oversight, and compliance support, as well as a strong Office of Sponsored Programs that provides both pre-award services including budget review and subcontracting, and post-awards management of grant finances. The University of Texas Health Science Center–Tyler will open become Texas’s newest medical school in 2022 and will integrate with The University of Texas at Tyler academic campus. The integration will expand collaborative opportunities to the nursing and pharmacology schools, as well as others that will soon become part of the school of medicine. Additional personnel will be available through this affiliation to participate in future CCTS research projects, including supplements supporting clinical research projects related to COVID-19.

Similarly, UTRGV was recruited to extend outreach to the primarily Hispanic communities at the border with Mexico. The University of Texas Rio Grande Valley serves ~1.4 M Texans, of whom >28% live in poverty (Figure 1) and is the site of the newest medical school in Texas. The University of Texas Rio Grande Valley has now been integrated into the CRU in Brownsville to enable multisite clinical research. It is now supported by Clinical Trials Express, an infrastructure designed to streamline and centralize multisite clinical trials, to lower research barriers, and to limit administrative redundancies; it is now a contributor to and a user of the Clinical Data Warehouse, which today houses clinical data on 4.1 million individuals. The CCTS has also launched several initiatives at UTRGV, including workforce development to enhance diversity and good clinical practice.

## Advent of New COVID-19 Projects in Rural Texas

The CCTS vision to prepare Tyler and sociodemographically similar areas in Texas for future emergent events has proved prescient, and the timeline from invitation to COVID-19 research is shown in Figure 2. As COVID-19 cases surged in the state in late June–July, NCATS approached the CCTS with new clinical research opportunities (Box 1), initially to help to complete the national placebo-controlled trial to determine the value of convalescent plasma in patients hospitalized within seven days of the onset of COVID-19 symptoms. The University of Texas Health Science Center–Tyler has recruited 96 patients to date. We note that although early treatment with antibodies or late treatment with steroids or remdesivir +/- anti-rheumatoid arthritis drug have now been shown to be beneficial,<sup>16,17,18,19</sup> the value of convalescent plasma remains unclear, highlighting the ongoing significance of this trial in hospitalized patients. Additional projects include a COVID-19 database supported by the National COVID Cohort Collaborative (N3C) and the All of Us Research program, ACTIV-4 trials for testing anticoagulant strategies for outpatients and discharged patients at risk of thrombotic complications from COVID-19, and a project supported by the RADxUP program to survey and address testing disparities in vulnerable populations. The ACTIV-4 projects are national multicenter anticoagulant trials that either have been recently initiated or will soon be. These projects represent new collaborations among CCTS components, with the CCTS serving as a hub collaborating with other institutions across the country. Following the same CCTS framework, the COVID-19 database and surveillance projects have now been initiated at UTRGV in south Texas, extending the same trials being conducted at UT Houston.

## Pressure to Launch

The University of Texas Health Science Center–Tyler, UTRGV, and UT Houston were under pressure to launch COVID-19 projects as cases surged in surrounding communities and in the United States in March–June 2020. Accordingly, the convalescent plasma trial received IRB approval at UTHSC-Tyler by reciprocity with UT Houston. This NCATS-designated high-priority clinical research initiative was implemented in August 2020, about a month after a mandate came from NCATS. Implementation involved using online communications to enable rapid collaboration among clinical and basic science faculty at UTHSC-Tyler, CCTS, and national principal investigators with input from NIH. Discovery and problem-solving sessions were and continue to be held to operationalize these large collaborative projects and manage logistics, to best use existing resources. Challenges that were addressed included training of less-experienced faculty on budget preparation, justification, time and effort commitment, and alignment with other clinical responsibilities. For example, family practice doctors at UTHSC-Tyler have little clinical research experience. They were asked to determine among themselves how to best integrate project needs with their busy practices. Notably, they developed a new paradigm that was unique among collaborating institutions, in which an institutional roster of COVID-positive individuals was used to identify potential trial participants. With IRB approval, this roster was used with telemedicine to enable physician oversight of recruitment and validation of informed consent.

In addition, all new investigators and staff recruited to support these projects were trained in responsible conduct of research, with compliance followed through the Office of Clinical Research. Similarly, subcontracting was accelerated, as were reviews of feasibility, project milestones, and accountability. The UTHSC-Tyler IRB was also reorganized to improve efficiency without compromising review, while the process to reconcile time and effort was streamlined. Collectively, these efforts enabled rapid implementation of COVID-19 initiatives, enhanced research capacity, and fostered new collaborations across Texas and the U.S.

The University of Texas Rio Grande Valley used the same CCTS framework and underwent similar realignments to launch the same COVID-19 research projects (Figure 2). It is important to note that this was the very first clinical research unit launched at UTRGV and they have since enrolled four patients into the convalescent plasma trial since January 2021, creating a new foundation for future research for the community. In particular, experienced staff developed and wrote the RADxUP surveillance project in collaboration with public health investigators at UTHSC-Tyler to quickly secure funding. The University of Texas Rio Grande Valley will lead RADxUP with UTHSC-Tyler as a subsite.

## Conclusions

The University of Texas Health Science Center–Tyler’s and UTRGV’s nimble and collaborative responses to COVID-19 mandates demonstrates that organizations in underserved and disadvantaged areas are fully capable of participating in urgent clinical trials, especially those that are of high national priority. The implementation of these trials was expedited with backing and mentorship as well as resources and logistical support made

available through the CCTS. Initiatives to lower research barriers (e.g., IRB reciprocity) were also essential to accelerate implementation. Importantly, this experience has attracted the support of the NIH/NCATS for future research initiatives not only at UTHSC-Tyler but also at El Paso and Rio Grande Valley. Current and future collaborative federal projects may provide these communities with early access to testing of potential medical breakthroughs for COVID-19 and for future biomedical challenges.

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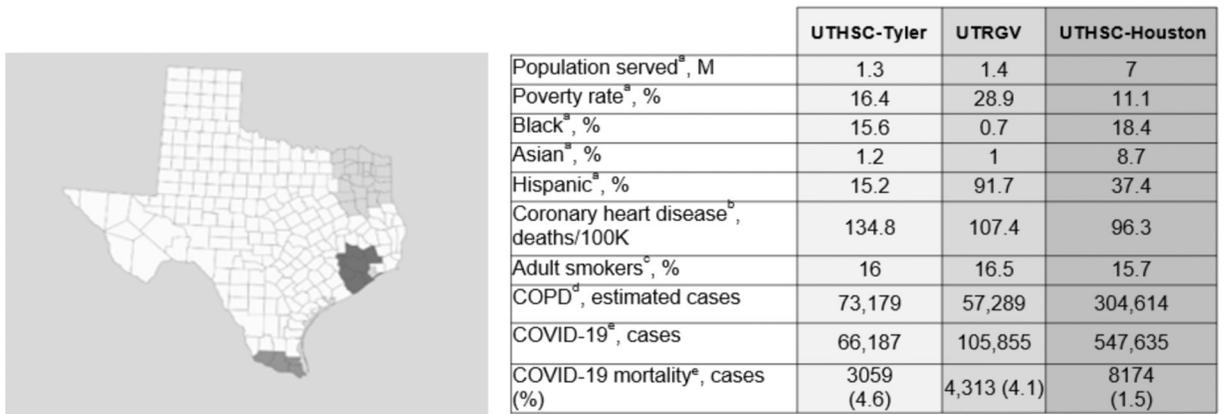
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**Box 1.****COVID-19 PROJECTS AT UTHSC-TYLER AND UTRGV AS OF MAY 5, 2021**

Grant No.	Title	Status at UTHSC-Tyler	Status at UTRGV
3UL1TR003167-02S2	Convalescent Plasma to Limit Coronavirus-Associated Complications (CONTAIN)	Accrued 96 participants	Accrued 4 participants
3UL1TR003167-02S3	N3C Data Enclave	Contributing data	N/A (data from catchment area collected by UT Brownsville)
3UL1TR003167-02S1_ap	Understanding and Addressing COVID-19 Testing Disparities in Vulnerable Populations: A Multilevel and Multi-method Approach	Initiated	Initiated
ACTIV-4 Outpatient	Anticoagulant versus aspirin or placebo for COVID-19 patients predisposed to vascular complications	Initiated	Initiated
ACTIV-4 Convalescent	Anticoagulant versus aspirin or placebo for COVID-19 patients predisposed to vascular complications	Initiated—Enrollment to begin May 2021	Initiated—Enrollment to begin May 2021



**Figure 1.** Catchment areas and communities served by UTHSC-Tyler, UTRGV, and UTHSC-Houston.

Note:

Data sources: <sup>a</sup>US Census Bureau (<https://www.census.gov/>)

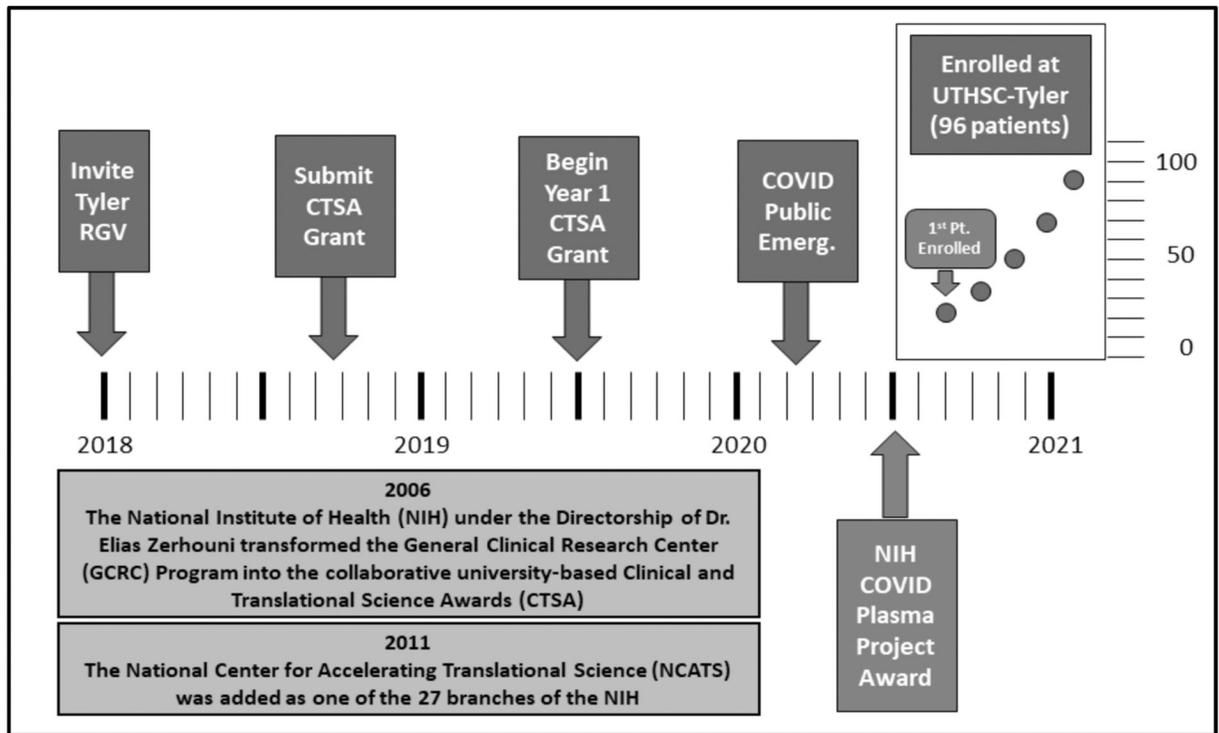
<sup>b</sup>Centers for Disease Control and Prevention (<https://nccd.cdc.gov/dhdspatlas/reports.aspx>)

<sup>c</sup>County Health Rankings & Roadmaps (<https://www.countyhealthrankings.org/>)

<sup>d</sup>American Lung Association (<https://www.lung.org/>)

<sup>e</sup>Texas Department of State Health Services (<https://dshs.texas.gov/>)

The CCTS Hub catchment area population is 13.5M



**Figure 2.**  
Timeline: From invitation to join CCTS to current enrollment in COVID-19 research.

DEMOGRAPHICS FOR HOUSTON, RIO GRANDE VALLEY, AND TYLER AND APPROPRIATELY PROPORTIONAL ENROLLMENT FOR CONVALESCENT PLASMA

Table 1.

	CONTAIN Enrollment and Race/Ethnicity Data														
	UTHSC-Houston						UTHSC-Tyler						UTRGV		
	Not Hispanic or Latino		Hispanic or Latino		Total	Not Hispanic or Latino		Hispanic or Latino		Total	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	146	Female	Male	Female	Male	96	Female	Male	Female	Male	4
Asian	2				2										2
Black or African American	9	4			13	17	10			27					40
White	4	2	58	67	131	22	36	2	9	69	2	2	2	4	204
Total	13	8	58	67	146	39	46	2	9	96	2	2	2	4	246