

The general public may watch the proceedings live at:
<https://www.youtube.com/channel/UCSQqlc7NFQEGISPQs6Ar7IA/videos>

Convening of the Texas Child Mental Health Care Consortium (TCMHCC)

May 15, 2020

10:00 AM – 3:00 PM

Agenda

- I. Call to order and roll call**
- II. Review and approve the following item:**
 - a. Minutes from April 20, 2020 Executive Committee meeting
- III. Updates on the following activities associated with implementation of the TCMHCC. The full Executive Committee may review, receive and/or provide information and/or make recommendations from the items discussed and take appropriate action.**
 - a. Communications including action to approve one logo for TCMHCC Initiatives.
 - b. External Evaluation update including action to approve the Statement of Work.
- IV. Updates from the Research Workgroup regarding implementation of TCMHCC Research Initiative, including opportunities, challenges, questions and milestones achieved. The full Executive Committee may review, receive and/or provide information and/or make recommendations from the items discussed and take appropriate action.**
 - a. Update from research workgroup
 - i. Approval of detailed HUB (lead and co-lead) budget
 - ii. Approval of proposals from each network
 - iii. Open discussion regarding Research
- V. If necessary, closed session for consultation with attorney regarding legal matters, related to posted items, pursuant to Section 551.071 of the Texas Government Code**
- VI. Discuss, consider, and if appropriate, approve information and updates provided by the Baylor College of Medicine in the role of the Centralized Operations Support Hub (COSH), CPAN, TCHAT or CPWE Workgroups relating to implementation of the COSH. The full Executive Committee may review, receive, and/or provide information and/or make recommendations from the items discussed and take appropriate action.**
 - a. Demonstration of data management system by TRAYT
 - b. Update on implementation of CPAN, and 1-888 number
 - c. Update on implementation of TCHAT

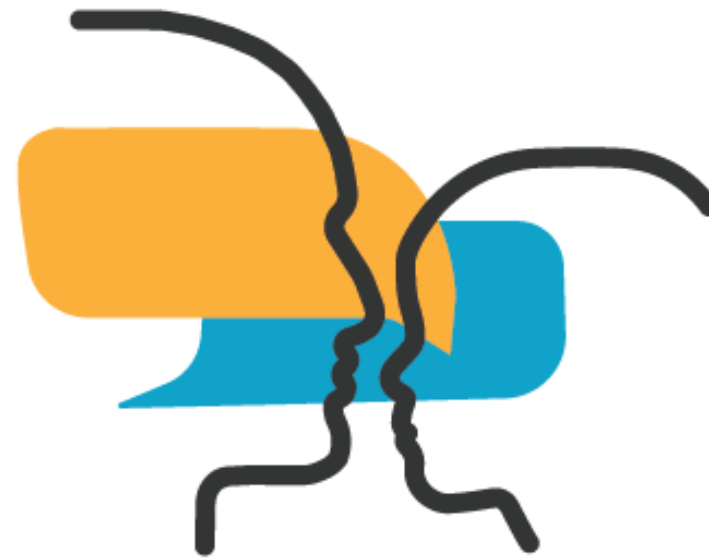
- d. Updates regarding other COSH related items identified by the Baylor College of Medicine and members of the Executive Committee

VII. Updates from TCHAT, CPAN, CPWE and CAP Fellowship Workgroups regarding implementation of these initiatives, including opportunities, challenges, questions and milestones achieved. The full Executive Committee may review, receive and/or provide information and/or make recommendations from the items discussed and take appropriate action.

- a. Update from TCHAT Workgroup
 - i. Open discussion regarding TCHAT implementation
- b. Update from CPAN Workgroup
 - i. Open discussion regarding CPAN implementation
- c. Update from CPWE Workgroup
 - i. Open discussion regarding CPWE implementation
- d. Update from CAP Fellowships Workgroup
 - i. Open discussion regarding CAP Fellowships implementation

VIII. Adjournment

Next meeting To Be Determined





The University of Texas at Austin
Dell Medical School

Charles B. Nemeroff, M.D., Ph.D. • Matthew P. Nemeroff Professor & Chair

Department of Psychiatry • Mulva Clinic for the Neurosciences

Health Discovery Building • 1601 Trinity St. Bldg. B • Austin, Texas 78712 • 512-495-5319 • cnemeroff@austin.utexas.edu

May 1, 2020

Childhood Trauma Research Network- Final Protocol

Charles B. Nemeroff, MD, PhD (UT-Austin Dell Medical School)

Karen Dineen Wagner, MD, PhD (UTMB)

Network: 11 sites in the SB 11 have enrolled to participate as Nodes with Node leaders

1. UT-Austin Dell Medical School-Hani Talebi, PhD
2. Baylor-Sophie Schneider, Ph.D
3. Texas A&M-Israel Liberzon, MD
4. Texas Tech-Michael Gomez, Ph.D
5. UT-Houston-Leslie Taylor, Ph.D
6. UT-San Antonio-Amy Garrett, Ph.D
7. UT-Southwestern-Sunita Stewart, Ph.D
8. UT-El Paso-Cecelia DeVargas, MD
9. UT-Tyler-Jeffrey Wherry, Ph.D
10. UTMB-Joseph Shotwell, MD
11. UT-RGV-Michael Escamilla, MD

At the UT-Austin Dell Medical School Hub, Jeffrey Newport, MD, Professor and Mark Bond, Ph.D, Assistant Professor, will serve to set up and manage the data base and and work closely with Mahdukar Trivedi, MD, Professor at UTSW, director of the Childhood depression/suicide research network. Asheigh Smith is an experienced research coordinator and she and her team will serve in this role for the childhood trauma network including training the research assistants at the 11 nodes.

The main goal of the childhood trauma network is to determine the mental health outcomes of children and adolescents in Texas exposed to trauma. In order to accomplish this goal we will be recruiting children and adolescents ages 8-20 years who have been exposed to trauma, broadly defined. This will include children exposed to a Criterion A Trauma as defined by DSM-5 AND children with more chronic trauma exposure (repeated child abuse and neglect, domestic violence, bullying, etc.) In Texas border regions and among immigrant and Mexican American communities, chronic trauma exposures may also include direct and indirect exposure to aversive details of family separation, migration journeys, and living in impoverished conditions. Subjects exposed to any trauma that fulfills the A criteria will comprise many of the children recruited into this study. These will therefore include children and adolescents who have personally experienced or witnessed trauma in the form of an acute medical emergency such as a gastrointestinal bleed, emergency surgery, serious cardiac event, sepsis, burns, automobile accident, as well as rape or assault, sudden loss of a parent, being present at a school shooting or other terrorist event, suddenly losing a close friend or family member (as for example to COVID-19). Operationally if a node wishes to recruit a subject into the network and has doubts about whether the acute or chronic trauma meets criteria, we will set up a rapid process for consultation with the Hub. With the broad inclusion criteria described above, it is clear that the various nodes will have various and differing recruitment sites for entry into the network. Recruitment sites include Level 1 trauma centers, emergency departments of children's

hospitals and general hospitals, pediatric and primary care clinics, and psychiatry hospitals and mental health clinics. Many of our potential referrals might come from the 13 children's advocacy centers serving abused children in the greater East Texas region. In addition, potential recruitment sites in South Texas may include community union advocacy centers (LUPE, ARISE Adelante) and alternative schools for emancipated adolescents who withdrew from high school due to their life situations, i.e. all girls schools for pregnant and young mothers, programs for adolescents who work, etc.

Once the potential subject is identified, informed consent for minors must be obtained from the parent or legal guardian and assent from the child/adolescent. Inclusion criteria will be the age of the subject (8-20 years), the ability to understand and speak English or Spanish as well the being able to see the assessment forms, hear instructions and function at a level that allows adequate completion of the assessment tools.

The patient and legal family guardian will be informed at the time of consent of the remuneration provided to them for participation in the study and the number and schedule of the follow up visits. Baseline and follow up visits at 1, 6, and 12 months will be scheduled with payment to be \$50 per visit.

Exclusion criteria: Subjects with current psychosis, pervasive developmental disorder or moderate to severe mental retardation; subjects who when interviewed are in severe pain, labor, respiratory distress or hemodynamically compromised.

As discussed during the teleconference, we are hoping to use a single IRB that all of the UT and non-UT schools can utilize. The IRB at UTSW was deemed the best choice in view of their previous history of approving large, multi-site studies.

Assessment

1. Demographic data- We will, as a group, discuss this to arrive at a consensus decision. Should include age, sex, Tanner stage (this is optional-some sites will be able to obtain from medical records, other may use self or parent report), family composition, year in school. Immigration status can be queried (optional).
2. Family History-Medical and psychiatric disorders
3. Past psychiatry History including previous (and current) medications and therapy.
4. Past Medical History including prior surgeries, medical trauma and medications. This would include permission to obtain past medical records. Not providing permission is NOT an exclusion criterion.
5. Any baseline laboratory data that is collected at the time of the trauma or in most recent medical records will be included in our data base (optional).
6. Psychological and Psychiatric Assessment-Some of the assessment tools will only be obtained at baseline whereas others will be repeated at each visit.
 - A. Structure Diagnostic Tool, MINI-KID – (15-50 minutes)
 - B. The Traumatic Events Screening Inventory (TESI)-child (20-30 minutes) and parent (10-30 minutes).
 - C. The Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5) which is now validated in children 6 years and older with a cutoff for PTSD diagnosis. (5-10 minutes)
 - D. A measure of the reaction of the child/adolescent at the time of acute trauma: the Immediate Stress Reaction Checklist (ISRC) which measures fear, helplessness and

horror, peritraumatic dissociation symptoms including numbness/detachment, derealization, depersonalization, etc. (5 minutes)

- E. A substance and alcohol screening tool, the CRAFFT, validated in children 12 and older. In addition, the NIDA screener: How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons? (< 5 minutes)
- F. A depression inventory, the PHQ-A. (< 5 minutes)
- G. A child anxiety inventory, Screen for Child Anxiety Related Disorders (SCARED), child and parent version. (10-15 minutes)
- H. A measure of school performance
- I. A suicidality scale, the CHRT-SR (< 5 minutes)
- J. A resilience instrument, the CD-RISC (5-10 minutes).
- K. Cultural Identity/Cultural connectiveness scale, EIS for Adolescents (< 5 minutes)]

A summary of the scales used and the estimated time for completion is provided at the end of this document.

Measure	Baseline	One Month	Six Months	Twelve Months
MINI-KID	X		X	X
TESI-C	X			
TESI-P	X			
PCL-5	X	X	X	X
ISRC	X			
CRAFFT & NIDA Screen	X	X	X	X
SCARED-C	X	X	X	X
SCARED-P	X	X	X	X
CHRT-SR	X	X	X	X
CD-RISC	X			
EIS	X			
SAS-School Scale	X	X	X	X

Budget: As discussed by Dr. Tamminga, we are anticipating a budget of \$250,000 per node in the Childhood Trauma Network over the entire funding period. This should provide ample funding for support for each of the node leaders and a research assistant with primary responsibility for recruitment and assessment of subjects as well as follow up. Patient remuneration will come from these funds as well.

Scale	Measure Of	Completed By		No. Items	Est Mins
		Child	Parent		
MINI Intl. Neuropsychiatric Interview (MINI-KID)	Diagnosis	Child			15-50
Traumatic Events Screening Inventory (TESI-C)	Traumatic Event(s)	Child	Parent	24	20-30
Immediate Stress Reaction Checklist (ISRC)	Trauma Reaction	Child		27	10
PTSD Checklist for DSM-5 (PCL5)	PTSD symptoms	Child		20	5-10
Patient Health Questionnaire for Adolescents (PHQ-A)	Depression	Child		9	5
Screen for Child Anxiety Related Disorders (SCARED)	Anxiety	Child	Parent	41	10-15
CRAFFT & NIDA/NIAAA Screener Questions	Drugs / Alcohol	Child		8	5
Concise Health Risk Tracking – Self Report (CHRT-SR)	Suicidality	Child		7	5
Connor-Davidson Resilience Scale (CD-RISC)	Resilience	Child		25	5-10
Social Adjustment Scale-School scale	School performance	Child		7	5
Ethnic Identity Scale (EIS)	Cultural Identity	Child		17	5
				Total	90-150

“THE COSH REPORT”

- Laurel L. Williams, DO
- Jennifer Evans



WELCOME TO THE ZOOM



HOW MANY MEETINGS AGAIN?

- Telecommunications
- Data Management
- CPAN
- TCHAT
- State Wide Referral System

TELECOMMUNICATION



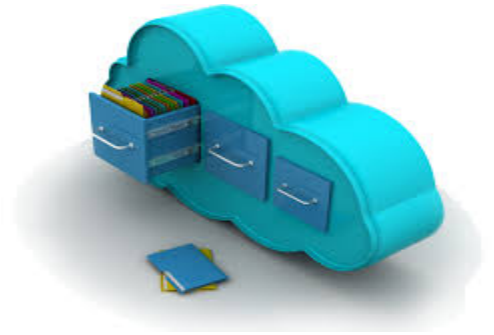
- ***1 800 901 CPAN (2726)- IT WORKS!***
- Lantana Contract is ALMOST Signed May x, 2020
- Lantana Project Manager will be Assigned ASAP
- Project Manager will connect with each HRI IT/Telecommunication Teams
- COSH created interim Phone Tree- All HRI CPAN Options Ring to BCM CPAN Team for Triage

DATA MANAGEMENT



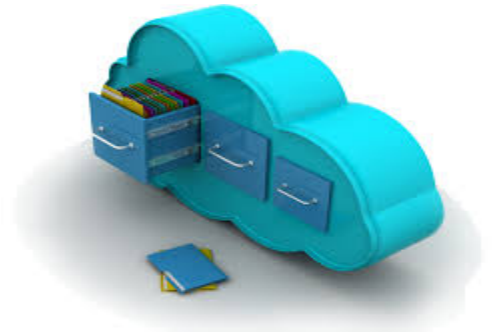
- BAA Master Agreement in Progress- Expect BAA to be signed mid-June
- Data Governance Committee 1st Meeting
- Trayt Building CPAN Platform- daily meetings with COSH
 - CPAN Committee had demo 2 weeks ago
 - Once NDA signed Trayt can provide CPAN demo to HRI Teams
- Weekly COSH and TCMHCC Business Operations Meeting

DATA MANAGEMENT



- RedCap Interim Solution Deployed for CPAN
- COSH working with BCM and Trayt to Get Contract Written and Signed June 2020 timeline
- COSH Scheduled meeting with all HRI IT/Compliance Teams to review TRAYT SPECS for May XX, 2020.
 - The HRI teams will be asked to send question pre-meeting. Teams will get written specs on Trayt prior
 - The meeting will be recorded for teams who cannot attend
 - Follow-up to meeting with individual Teams as needed

DATA MANAGEMENT



- Data Governance Committee Met May 14, 2020
- Recommendations for Chair and Vice Chair for the group was Daniel D and Steven P respectively
- Team members: Laurel W, Andy H, Sonja G, Alan P, Alex V, Jennifer E, Lashelle I, Octavio M
- Mission: Daniel will review
- Goals: Daniel will review

CPAN GO LIVE MAY 18, 2020



- 8 CPAN Teams are Fully Operational
- 4 CPAN Teams will Deploy in next few months
- CPAN Physician Training/Recorded May 4, 2020 Drs. Barry Sarvet and Seema Shah
- COSH Created CPAN Box to Provide access to CPAN Teams critical process maps and materials

CPAN GO LIVE MAY 18, 2020



- COSH Created Additional Videos to assist with Training for Enrollment, PCP Phone Engagement, Team Transfers, Using RedCap
- COSH has had 22 meetings (2 meetings per CPAN team) to review Team structure, processes, and problem solve
- COSH providing CPAN Team Practice Calls

CPAN NEXT STEPS



- Tract Enrollment goes live May 18, 2020- BCM will start first, once BAAs Signed and HRI Sign Off Tract will deploy to each HRI
- COSH will develop Total CPAN Team Meetings to address:
 - Quality
 - Consistency of CPAN processes
 - Build out for CPAN Website Information
 - Decisions on CPAN Algorithms for Management of Common Disorders

TCHATT UPDATE



- COSH has had 15 individual TCHATT team meetings- challenges, processes
- COSH along with TCHATT Committee Chairs and TCHATT teams have met with TEA Leadership twice to review TCHATT aims
- Phase 1 Teams able to go-live with TCHATT this academic year include: UTSW, UTMB, Tech Lubbock, & BCM, pivot to Tele to Homes

TCHATT UPDATE



- COSH created TCHATT BOX - for all HRI TCHATT teams share information, processes
- COSH is recommending all HRI TCHATT teams consider standard outcome measures to track quality of care. Not research –addresses outcomes
- Trayt can easily track outcomes
- COSH will set up similar ALL TCHATT team meetings to review areas of commonality (such as measurement based care)

STATE WIDE REFERRAL SYSTEM



- Both CPAN and TCHATT need an organized and up to date referral system process
- COSH met with Sonja Gaines and her HHS team to review resources
- COSH setting up meeting with FHQC State Leadership
- Welnity Project- statewide initiative to connect providers and locate appropriate services

COSH QUESTIONS?



Texas Child Mental Health Care Consortium External Evaluation Scope of Work

Background

The Texas Child Mental Health Care Consortium (TCMHCC) was created by the 86th Texas Legislature to leverage the expertise and capacity of the health-related institutions of higher education to address urgent mental health challenges and improve the mental health care system in this state in relation to children and adolescents.

Vision

All Texas children and adolescents will have the best mental health outcomes possible.

Mission

Advance mental health care quality and access for all Texas children and adolescents through inter-institutional collaboration, leveraging the expertise of the state's health-related institutions of higher education, local and state government agencies, and local and state mental health organizations.

Structure

The TCMHCC is composed of the following entities:

- The 13 state-funded health related institutions of higher education in Texas,
- The Health and Human Services Commission,
- The Texas Higher Education Coordinating Board (THECB), which will receive the funding from the state and send it to the Consortium members,
- Three nonprofit organizations that focus on mental health care: Meadows Mental Health Policy Institute, Hogg Foundation for Mental Health, and the Texas Council of Community Health Centers,
- The 13 state-funded health related institutions of higher education in Texas,
- The University of Texas System, which is the administrative support entity, and
- Any other entity that the executive committee considers necessary.

Implementation Goals

- Create a consortium to help coordinate children's mental health initiatives across Texas' publicly funded health-related institutions of higher education;
- The Child Psychiatry Access Network (CPAN) will be a network of academic hubs that provide telemedicine-based consultation and training to pediatricians to assist them with identifying mental health issues in their patients. CPAN will deploy first in those regions where an existing infrastructure can be exploited, or a new infrastructure can set up quickly. The objective is to enroll 75% of primary care practices in the covered

regions by the end of the second year of implementation. The network will consist of the following components:

- State-wide telephone system that responds to calls from primary care providers within 5 minutes, and if immediate assistance is needed connects the provider with a child and adolescent specialist within 30 minutes.
- State-wide data management system that tracks calls and responses in order to measure both need and responsiveness.
- Educational content for primary care providers, developed by CPAN members, to assist in assessing and referring children and adolescents with behavioral health needs.
- Marketing to raise awareness of CPAN services and to disseminate educational material.
- The Texas Child Health Access Through Telemedicine (TCHAT) program will create or tap into existing telemedicine or telehealth programs to assist school districts with identifying mental health care needs and accessing services. In order to efficiently make use of state funding, TCHAT deploys first in those regions where an existing infrastructure can be expanded, or a new infrastructure can be set up quickly. The program will consist of the following components:
 - Telepsychiatry or counseling services for children and adolescent within the schools.
 - Educational and training materials for school staff to assist in assessing, supporting, and referring children and adolescents with mental health needs.
 - Analysis and mapping of existing telemedicine and telehealth programs that are currently providing, or can be adapted to provide, services to schools.
 - State-wide data management system that tracks calls and responses in order to measure both need and responsiveness.
- The Consortium will support the expansion of the child and adolescent psychiatry workforce in Texas through two means.
 - Funding full-time psychiatrists to serve as academic medical directors at community mental health providers as well as new resident rotations at those facilities
 - Funding additional fellowship positions in child and adolescent psychiatry at the state-funded health related institutions.
- The goal of Research workgroup, under the supervision of the Executive Committee, is to propose and ultimately fund 2-3 multi-institutional research projects in areas that have potential for advancing mental health care for children and adolescents in Texas. Only superior scientific projects focused on health services will be considered for funding. .

Scope of Work

The External Evaluator will conduct an independent, external, program-specific, and comprehensive evaluation to provide policymakers and Consortium members with assessments that can guide quality improvement and decision-making for future program planning and implementation.

The evaluation will center on a systematic approach to planning with program-specific comprehensive evaluations. The evaluations will use mixed quantitative and qualitative methods, with a specific focus on implementation science, quality improvement, and health economics. Focus will also include participatory approaches to engage stakeholders affected by the programs.

The overall goal of the independent evaluation will be to provide policymakers and Consortium members with program outcome assessments to guide quality improvement and inform the consortium and legislature as they deliberate about future program policies, implementation, dissemination and financial planning. The project will include a formative (process) summary to document the initial implementation, as well as preliminary summative (outcome) and cost analysis evaluations.

Elements will include:

1. Analysis of demographic, clinical, and outcome data collected by the Consortium,
2. Assessment of satisfaction of Consortium consumers, including people served, their families, school personnel involved in TCHAT, and primary care practices involved in CPAN,
3. Assessment of outcomes of children and families served by CPAN and TCHAT programs. This should include multiple data sources, in addition to archival data available through the Consortium,
4. Analysis addressing health disparities and equity in outcomes across sites, with specific focus on barriers to access related to cultural, linguistic, and geographic factors, and
5. Recommendations to improve fidelity of implementation to legislative priorities and services outcomes.

Requirements

To be eligible to apply for the role of Independent Evaluator, you must be a Texas university or coalition of Texas universities. Texas schools of medicine may not apply to be part of the external evaluation contract.

Budget will not exceed a maximum of \$750,000 total for the Fiscal Years 2020 and 2021 combined. Principle Investigator(s) and senior staff must have experience in the following areas:

- Mixed methods research,
- Quantitative and qualitative methods, with a specific focus on implementation science, quality improvement, and health economics,
- Implementation science, quality improvement, and health economics.
- Mental health research and evaluation,
- Health services research and evaluation,
- Health policy and systems research and evaluation, and
- Peer reviewed publications related to children's mental health services evaluation.

Deliverables (including timelines)

The deliverable schedule below assumes a start date in June 2020.

Date	Deliverable	Description
7/2020	Presentation on evaluation plan to Consortium	Draft plan to review with Consortium in July for final approval by Consortium
12/2020	Present on findings to date to Consortium	Present initial findings and feedback on implementation progress to Consortium
3/2021	Interim report on implementation progress for legislative oversight	This report will focus on implementation progress and recommendations to improve fidelity of implementation to SB11 requirements
8/2021	Final report on implementation progress and initial outcomes	This report will be the final report for the biennium and include recommendations to improve both fidelity of implementation and outcomes

DRAFT 05.13.2020

DEPRESSION HUB (UTSW Lead/TTUHSC Co-lead)				TRAUMA HUB (UT Dell Lead/UTMB Co-lead)			
EXPENSE	06/20-08/20 FY2020	09/20-08/21 FY 2021	TOTAL	EXPENSE	06/20-08/20 FY2020	09/20-08/21 FY 2021	TOTAL
SALARY – FACULTY POSITIONS	\$ 117,344	\$ 437,919	\$ 555,263	SALARY – FACULTY POSITIONS	\$ 135,063	\$ 540,250	\$ 675,313
0.25 Network Scientific Lead				0.25 Network Scientific Lead			
0.25 Network Co-lead				0.25 Network Co-lead			
0.8 Faculty Project Manager				0.6 Faculty Project Manager			
0.75 Statistician				0.75 Ass't Prof/Statistician			
0.4 FY20, 0.1 FY21 Psychologist Training Lead				0.3 Psychologist Training Lead			
SALARY – OTHER POSITIONS	\$ 127,659	\$ 510,638	\$ 638,297	0.2 Database Architect			
1 Database Architect				SALARY – OTHER POSITIONS	\$ 101,326	\$ 405,300	\$ 506,626
1 Sr Research Site Manager				0.65 Sr Research Site Manager			
1 Sr Research Site Manager				1 Senior Research Site Manager			
0.2 Network Administrator				0.2 Network Administrator			
1 Data Manager				0.75 Data Manager			
0.5 Regulatory Manager				0.5 Regulatory Manager			
1 Project Research Assistant				1 Project Research Assistant			
0.2 Senior Accountant				0.2 Senior Accountant			
0.75 Admin Associate				0.75 Admin Associate			
0.2 HR Associate				0.2 HR Associate			
FRINGE	\$ 56,037	\$ 221,854	\$ 277,891	FRINGE	\$ 70,443	\$ 281,773	\$ 352,217
TRAVEL	\$ 14,400	\$ 57,600	\$ 72,000	TRAVEL	\$ 14,400	\$ 57,600	\$ 72,000
EQUIPMENT	\$ 20,000		\$ 20,000	EQUIPMENT	\$ 20,000		\$ 20,000
Data Server				Data Server			
CONTRACTS	\$ 315,000	\$ 94,000	\$ 409,000	CONTRACTS	\$ 315,000	\$ 94,000	\$ 409,000
Website Development, Database and Reporting Systems Development, and Training Materials and Videos				Website Development, Database and Reporting Systems Development, and Training Materials and Videos			
MATERIALS	\$ 38,285	\$ 21,070	\$ 59,356	MATERIALS	\$ 36,600	\$ 14,500	\$ 51,100
Computer, iPads, Study Materials, Informational Materials, Conference Calls, Server Maintenance				Computer, iPads, Study Materials, Informational Materials, Server Maintenance			
TOTAL	\$688,725	\$1,343,082	\$2,031,807	TOTAL	\$ 692,832	\$1,393,423	\$2,086,256

Texas Child Mental Health Care Consortium Research

Youth Depression and Suicide Research Network

Title of the Research:

PIs: Madhukar H. Trivedi, MD and Sarah Mallard Wakefield, MD

The goal of the research component of the TCMHCC is to examine highly impactful research areas in child mental health, where great need exists, and where health services research can make a significant contribution to child mental health care where aligned with the state-wide Behavioral Health Strategic Plan.

1. What is the overall purpose of the study?

The purpose of this study is to improve the evaluation of and response to the increasing problem of youth depression and suicide in Texas by coordinating a research network of Health-Related Institutions across the state.

2. What are the objectives? List each objective separately.

- a. Evaluate the healthcare system in Texas as it relates to screening, responding, and monitoring youth symptoms indicative of depression and/or suicidal behaviors.
- b. Examine if the different ways in which youth depression presents in a primary care setting (i.e. sad v. irritable) might correlate with a best response with certain treatment (i.e. cognitive behavioral therapy v. supportive therapy).
- c. Build research capacity in Health-Related Institutions across the state with high fidelity to research methods and protections for human subjects.
- d. Increase opportunities for future federal funding for research that would benefit Texas citizens and further the missions of Health-Related Institutions in Texas.

3. How does the study address current gaps in services?

- a. Depression and suicide impact a significant number of Texas youth. According to the 2017 Youth Risk Behavior Survey Texas data brief, 17.8% of Texas high school youth reported having serious thoughts about suicide, 14.5% made a plan, 12.3% attempted suicide, and 4.5% reported having made a suicide attempt that required medical attention in the last 12 months. Texas high school students had a 66% higher rate of attempted suicide compared to the U.S. average (12.3% in Texas vs. 7.4% in U.S.).
 - i. Many Texas communities lack the education, resources, and infrastructure needed for early detection and evidence-based treatment.
 1. Clinic sites within each node will be required to provide evidence-based depression care for youth, which includes:
 - a. Universal screening

- b. Use of the collaborative care model to improve patient outcomes, save money, and reduce stigma related to mental health.
 - c. Measurement-based care (MBC)
 - i. Using research-validated self-report scales
 - ii. Systematic assessment of symptoms
 - iii. Systematic assessment of treatment side-effects
 - iv. Adherence to defined intervals
 - ii. Many pediatric providers remain reticent to treat mental health concerns, leading to inconsistent identification and treatment of depression (Wissow et al, 2017).
 - 1. In conjunction with this research study, the Network’s lead team, in collaboration with Node leadership, will offer educational and consultation opportunities for partnering clinics.
 - 2. Clinic-level data will be provided in reports and dashboards to partnering clinics to enhance engagement and provide real-time feedback to improve processes.
- b. Substantial gaps exist in knowledge related to clinical, functional, behavioral, social, and biological mechanisms of depressive disorders as related to an individual’s risk of developing depression, ability to cultivate resilience, and response to treatment.
 - i. This study will identify risk markers, indicators of onset, long-term (natural) course of disease, and treatment-associated outcomes in order to improve early and accurate response to depressive symptoms in youth.
- c. While Texas has several large research institutions, many of the Health-Related Institutions across the state are focused primarily on clinical care and do not have significant research infrastructure.
 - i. Establishing a Network of Health-Related Institutions across the state leverages the infrastructure and expertise of larger Health-Related Institutions to support smaller Health-Related Institutions. Each Node will receive significant training as well as maintenance visits from the Network Hub to ensure high fidelity to research methods.
 - ii. Establishing a Network across a state as varied as Texas will allow for investigation of a more diverse population and provide specific information that can be applied more accurately for each region.
- d. Large grant opportunities are highly competitive and are often awarded to those with significant past proven research experience, to those with significant pilot data, or to those with access to a large population so that the results might provide more generalized data to be utilized across the nation.
 - i. Each Network will include researchers with significant past proven research experience in addition to more junior researchers from across the state thus merging high level research expertise and mentorship for junior researchers.
 - ii. Through the Network, all Node members will have access to pilot data for future grant applications.

- iii. The possibility of the vast and varied population who can engage in research with the Network is likely to result in highly competitive future grant applications and generalizability of the results.
- 4. In 5-years,
 - How can you foresee this research can inform clinical practices? This research will standardize MBC in the clinical setting to support our primary care clinicians across the state and provide Texas youth with early screening and intervention for symptoms associated with depression and suicide.
 - How could it inform public policy? This research will provide predictive models for short and long-term outcomes associated with youth depression and suicide and will identify regionally specific and state-wide service delivery gaps in order to inform the next best targets for policy makers and legislators to improve the health care of youth in Texas.
- 5. List the methods which will be used in achieving this research.
 - a. Building the Network
 - i. All 13 sites represented in SB11 have been invited to participate in the Youth Depression and Suicide Research Network as “Nodes.” Each Node who has indicated desire for participation has obtained support of senior institutional leadership including the department chair. Leadership from each Node provided input and edits in the study design process by committee.
 - ii. Nodes will identify leadership and staff to manage the study in each region. Nodes will develop partnerships with primary care, pediatric, specialty care, and/or community clinics to implement the study. Once all Nodes and clinic sites have been identified and training is completed, the Youth Depression and Suicide Network will launch.
 - iii. Nodes will have a target subject volume of 400 patients over the course of 1.5 years, and they will be required to work closely with Network leadership to recruit, monitor, and retain participants. This will require active engagement and sustained relationships with clinics within the academic medical center as well as clinics in the community (i.e., psychiatry, psychology, counselling).
 - b. Study Design
 - i. Participating clinic sites will be monitored for universal screening and use of MBC and collaborative care, with metrics collected for each aim.
 - ii. Nodes/sites will refer youth and parents to the Patient Registry, where data will be collected.
 - iii. Youth patients of participating clinics (ages 10-18) who screen positive for depression or suicidality (defined as suicidal ideation or behavior), and their parents, will be recruited for participation in the Network Registry Study.
 - iv. If parent and youth consent/assent, baseline data will be collected regarding mood symptoms, suicidal ideation and behavior, associated comorbidities, treatment history, services use, and social determinants of health.
 - v. Youth participants and parents will be sent monthly measures through the Electronic Data Capture (EDC) system developed and maintained by UT

Southwestern. Additionally, measures will be given at provider visits to support delivery of measurement-based care within the clinics.

6. What types of data that would be collected for this research?

Demographic data, psychiatric history, medical history, family medical and psychiatric history, and psychiatric and psychological assessments.

7. How will the data be secured?

- a. A TCMHCC Data Management Plan will be developed by the HUB Research data management includes the:
 - i. Definition of required study data
 - ii. Design of databases and case report forms
 - iii. Data entry process
 - iv. Development of a data dictionary
 - v. Access and permissions to documents and data
 - vi. Collection and storage of participant details and study data
 - vii. Quality control and assurance of data
 - viii. Data archiving and destruction
 - ix. Data access permissions for analysis ready data
- b. Data will be collected through TCHMCC Research Electronic Data Capture (EDC) System, a self-managed, secure, web-based software solution designed to support data collection strategies for clinical research studies. The EDC system software helps researchers quickly develop databases for collecting and managing research data. All of the sites participating in the study will have permission to submit validated data forms and receive feedback, alerts, or notifications from the EDC system as well as receiving reports and validation queries using secure transmission technology.
- c. Risk of breach of confidentiality will be minimized by the following measures:
 - i. Personal identifying information (i.e. name on informed consent, data of birth) will be recorded on a paper source, will be cross-referenced with a de-identified participant number, and will be stored in a separate binder and this binder will be locked in a file cabinet.
 - ii. De-identified data will then be coded and entered into password-protected databases on password-protected and encrypted computers in locked offices. Data will be shared and analyzed in a de-identified manner only.
 - iii. For the Network Registry Study, only de-identified information will be entered.
 - iv. All users of the EDC system will be tracked and provided access in a secure fashion following established SOPs for this process.
 - v. As with all research data, information gathered by the study will be used only for aggregate analysis; it will not be released with any information that identifies research participants.
 - vi. The data managers, statistician, Investigator, and Sponsor do not have access to the identities of patients. That information is retained only at the clinical centers and will be de-identified prior to being uploaded into the repository for data synthesis and analyses.
 - vii. Uses and risks related to data collection will be outlined in the informed consent and reviewed with the participants.

8. How will people impacted by this issue be incorporated in the design and implementation of the protocols?

Family and youth engagement experts from the Hogg Foundation for Mental Health, Texas Institute for Excellence in Mental Health, and Texas HHSC have been invited to participate in the Network planning calls. These engagement experts will provide vital input into the overall protocol design especially as it relates to connecting with and protecting youth and family members.

9. What types of information would be provided as a result of this research?
 - a. A descriptive summary of the data by participating network nodes as well as by various socio-demographic characteristics of the participants such as age groups, gender (as a biological variable), urban or rural, degree of fidelity to MBC, etc.
 - b. Predictive models for treatment outcomes and trajectories of disease course
 - c. Models to assist with treatment selection that may benefit subgroups of participants.

10. How do you see that data/information utilized by:

- a. Clinicians:
 - i. Development of practical tools to evaluate risk and guide treatment that can be translated back into clinical and community-based settings
 - ii. Improvement in education and treatment recommendations to youth, parents, and families who present with risk factors for depression.
- b. Researchers:
 - i. Improved understanding of disease development in young people to guide future treatment-related research.
 - ii. The development of predictive models will inform future research related to differences in disease presentation.
 - iii. Understanding current gaps regionally and across the state, and how this affects disease burden and treatment outcome will inform future research related to improved treatment delivery models.
- c. Policy Makers
 - i. The development of predictive models will allow educators, other youth-related stakeholders, and policy makers to advocate for the most effective and efficient screening and response models for youth depression and suicide.
 - ii. Information obtained in this study will help youth advocates and policy makers direct funds toward projects that have the highest likelihood to close screening and service delivery gaps for youth.

11. HUB Details:

- a) What is the role of the HUB in the research?

The role of the HUB is to support the 11 nodes and enable them to carry out the work of subject recruitment and data collection. As such the HUB personnel will train each of the node sites on precisely how to collect the subject data step by step. This will be accomplished by in person visits to the node sites on a regular basis. Once the data is obtained, it is available to all members of the network for data analysis and generation of publications. The HUB will provide the statistical expertise to enable the node faculty/investigators and members of the TCMHCC executive committee to query the data base to address important issues in the depression field.

b) List activities of the HUB.

The primary responsibilities of the HUB is to provide oversight on all aspects of study design and implementation. The following activities are directed by the HUB:

- Designing the protocol (in collaboration with the node members and other interested parties)
 - Establishing the parameters of assessment schedules
 - Selecting measurement tools
 - Developing forms
 - Coordinating additions / changes to the protocols
 - Evaluating the latest research findings, and updating the study MBC standards as these need to evolve based on the latest research
 - Convening a coordinating committee to provide input on updating protocol changes
- Establishing and implementing monitoring parameters
 - Training Sites on regulatory requirements
 - Carrying out ongoing monitoring of study data and recruitment
 - Providing coaching to Site investigators and coordinators
- Supervising all of the Node and Site research activities.
 - Training researchers in the use of the measurement tools, forms, and monitoring procedures
 - Training Site providers on the latest evidence guiding MBC, with additional training as new evidence is discovered and study MBC standards are revised.
 - Convening Node research leads in regular conference calls to review study progress (weekly at first, tapering to monthly by year two)
- Overseeing data management, statistical analyses, and preparation of progress reports as required.
 - Developing the research database.
 - Training all study personnel on process for data entry and data query response.
 - Developing data query strategy.
 - Monitoring Site responses to data queries.
 - Carrying out core data analysis on behalf of the network for augmentation by hub researchers.
- Monitoring federal grant opportunities and providing technical support to all network related federal grant proposals
 - Extending funding opportunities for Node researchers to participate in multi-site federal grants already overseen by the hub, as well as new grants
 - Mentoring junior researchers from Nodes or Sites in the first year to submit new federal grants

These activities will be accomplished by the HUB team as follows (additional details regarding responsibilities are provided in Section e below):

Network Scientific Lead. Oversee all aspects of study development, implementation, interpretation of results, and dissemination.

Network Co-Lead. Assist Network Scientific Lead in all aspects of the study, including Node coordination.

Faculty Project Manager. Coordinating the day-to-day operations of the Network, including working with all Node investigators and Sites to ensure successful implementation of the research projects implemented across the network, such as day-to-day management of start-up, study operations and procedures.

Statistician. Conducting all statistical analyses and overseeing the data management process.

Psychologist Training Lead. Developing the training program, conducting training workshops, and providing ongoing rating calibrations and re-certifications.

Senior Research Site Manager. Ensuring project deliverables are met in a timely manner, developing reports, communicating with Nodes and with the state, organizing meetings, traveling to sites to review recruitment and data integrity. Two Senior Research Site Managers will each be responsible for overseeing half of the Nodes.

Project Research Assistant. Assisting research team with data management, data query tracking, creation of reports, etc.

Network Administrator. Assisting with protocol development and providing oversight on budget and study administration.

Regulatory Manager. Providing oversight of all regulatory requirements for the study, and monitoring Nodes and Sites for adherence to regulatory requirements.

Senior Accountant. Overseeing study funding, fiscal accountability, fund disbursement, and funding reporting requirements.

Administrative Associate. Completing administrative tasks for the Network, including purchasing, travel arrangements, meeting scheduling, and coordinating communications across the Network.

Human Resource Associate. Coordinating Human Resource administration.

Database Architect. Developing the database system, user interface, data query system, and outcome reports.

Data Manager: Assisting the Database Architect with developing database and user interface, training Sites on data entry and queries, overseeing data monitoring/cleaning.

- c) List the proposed key staff for the HUB.

Faculty

Madhukar H. Trivedi, MD – Network Scientific Lead
Sarah Mallard Wakefield, MD – Network Co-Lead (TTUHSC)
Jennifer Hughes, PhD – Faculty Project Manager
Abu Minhajuddin, PhD – Statistician
Joseph Trombello, PhD – Psychological Training Lead
Carol Tamminga, MD – TCMHCC Research Chair

Staff

Afsahena Rezaeizadeh, RN – Senior Research Site Manager
Maria Monastirsky – Senior Research Site Manager
Taryn Mayes – Network Administrator
Jon Zimmerman – Database Architect
Tianya Wang – Data Manager
TBD – Regulatory Manager
Sahayog Thapa – Senior Accountant
Ericka Hardman – Administrative Associate
Robyn King – Human Resource Associate

* Fringe benefit rates are based on a matrix developed by UT Southwestern, and are dependent on the employee's salary and premium sharing coverage. Fringe benefit rates include FICA matching, retirement benefits, vacation/sick accruals, Worker's Compensation insurance, unemployment compensation insurance, etc.

Faculty:

Madhukar H. Trivedi M.D., Network Scientific Lead. Dr. Trivedi is Professor and Chief of the Division of Mood Disorders in the Department of Psychiatry, and Director of the Center for Depression Research and Clinical Care. He has extensive experience in the implementation of clinical trials and the evaluation of factors that influence disease development and course, as well as treatment response, for depressive disorders. He has served as PI on many major NIH Funded multi-site grants that include both academic and real-world clinical practice centers and has demonstrated success in collaborating with a broad range of clinicians and investigators.

Dr. Trivedi's responsibilities in the proposed study include designing the protocol, establishing the parameters of assessment schedules, selection of measurement tools, developing forms, establishing monitoring parameters and supervising the faculty and staff of the Network Hub, as well as the Data Management Center (including data collection, management, and coordination). He will ensure that project goals are met in a timely manner with integrity, that the work is done within budgeted amounts and is in compliance with University requirements, that participant recruitment progresses on schedule, and that data are collected and analyzed properly. Dr. Trivedi will visit each of the Node regularly and ad hoc when needed. Drs. Trivedi and Wakefield will also hold bi-weekly All Node calls to discuss the progress of the program and address safety and recruitment concerns. Dr. Trivedi assumes responsibility for health and safety standards and protection of Human Subjects. He together with Dr. Wakefield will also provide oversight leading and coordinating the Youth Depression and Suicide Network in all

aspects of study implementation, preparation and submission of progress reports, management of study funding, and preparation of manuscripts to disseminate study results. He has already engaged the Node leads and will continue to do so to establish consensus around all aspects of the study implementation. Finally, Dr. Trivedi, in collaboration with Dr. Wakefield, will provide mentorship to early career investigators at the Node and Site level.

Sarah Mallard Wakefield, MD, Network Co-Lead. Dr. Wakefield is an Associate Professor in the Department of Psychiatry at Texas Tech University Health Sciences Center. Dr. Wakefield will serve as the Co-Lead for the project. Dr. Wakefield is Director of Child and Adolescent Psychiatry Services at Texas Tech University Health Sciences Center School of Medicine and is the Chair of the Department of Psychiatry. Dr. Wakefield is clinically active in the field of child and adolescent psychiatry and works extensively with youth at risk for developing depression, youth with suicidal behaviors, and primary care clinicians who see youth with these symptoms. Dr. Wakefield's responsibilities in the proposed study include input on protocol design and collaboration with Dr. Trivedi as described above to ensure Node cohesion and coordination. Dr. Wakefield, in collaboration with Dr. Trivedi, will also provide mentorship to early career investigators at the Node and Site level.

Jennifer Hughes, Ph.D., Faculty Project Manager [80% FTE]. Dr. Hughes is an Assistant Professor of Psychiatry, and has extensive experience working with children and adolescents with depression and suicidal behaviors. Dr. Hughes will be responsible for coordinating the day-to-day operations of the Network, including working with all Node investigators and Sites to ensure successful implementation of the research projects implemented across the network. She will assist with the operational management of the trial, especially day-to-day management of start-up, study operations and procedures. She will assist with monitoring activities related to start-up, ongoing implementation, and study closure are occurring, and oversee personnel associated with the research infrastructure. She will provide guidance to regional infrastructure Node leadership, as well as regional Node staff. She will guide protocol implementation and assist with training and resolution of day-to-day issues related to the functioning and consistent implementation of the study. She will work with Nodes on recruiting sites, training, and study implementation. She will develop training materials and monitor quality of assessments at each node. She will assist Dr. Trivedi with communications to Node leadership. During the project start-up, Dr. Hughes with Dr. Trivedi will travel to each Node to work with investigators and study coordinators to provide training and to develop potential partner clinics. She and Dr. Trivedi will also visit each Node regularly and ad hoc when needed and seek guidance from Dr. Wakefield.

Abu Minhajuddin Ph.D., Statistician [75% FTE]. Dr. Minhajuddin, Professor with dual appointments in the Department of Psychiatry and Population and Data Sciences at UT Southwestern Medical Center. He has extensive experience with statistical analyses, and interpreting neuroscience data, and data detailing medical conditions. Dr. Minhajuddin will have primary responsibility for conducting all analyses of outcomes and will oversee the data management process. He will provide expertise and development of novel analytical approaches to the study of large and complex datasets and will also provide guidance on data management and contribute to study manuscripts. He will assist in writing manuscripts and progress reports.

Joseph Trombello Ph.D., Psychologist Training Lead [40% FTE in Year 1; 40% FTE in Year 2]. Dr. Trombello is an Assistant Professor in the Department of Psychiatry and leads the Center for Depression Research and Clinical Care Measurement Academy, in which he provides training to

internal and external clinicians on a variety of diagnostic and severity rating scales. Dr. Trombello will develop the training program for the Network and will conduct training workshops and individual training opportunities to investigators and research staff, as well as provide ongoing rating calibrations and re-certifications. The majority of the development of training materials and in-person trainings will occur in Year 1, with ongoing monitoring, re-calibrations, and training new staff in Year.

Other Staff:

Afsaneh Rezaeizadeh, RN, Senior Research Site Manager [100% FTE]. Ms. Rezaeizadeh has several years conducting clinical research and has served as a coordinator over several collaborative research studies involving multiple sites. She will serve as one of the two Senior Research Site Managers. The Senior Research Site Managers will each be responsible for half of the Nodes. They will ensure that all project deliverables are met in a timely manner and will be responsible for coordinating the Nodes to ensure ease of study implementation, participant recruitment, and data collection. In addition, the Senior Research Site Managers will be responsible for developing reports and other ongoing communications across the Nodes and with the state, and will assist with regulatory requirements, including managing the UT Southwestern IRB for this project. They will hold primary responsibility for organization of all meetings and associated tasks and data collection/analyses to be completed in between meetings and will work with Drs. Hughes and Minhajuddin to provide oversight and implementation of the Node site and Data Management Center. In addition, they will travel to their respective Nodes to provide training to Node Research Coordinators and will conduct regularly scheduled visits to each Node to review recruitment and data integrity. They will also hold weekly calls with the Node Research Coordinators to review recruitment progress, protocol changes, and data management issues.

Maria Monastirsky, Senior Research Site Manager [100% FTE]. Ms. Monastirsky has over 10 years of clinical trials experience and has provided oversight for several multi-site trials. Most recently, she manages the Data Coordinating Center for a large multi-site PCORI study involving over 20 sites. She will serve as one of the two Senior Research Site Managers. Ms. Monastirsky will take on additional responsibilities providing oversight for the Data Management Center.

TBD, Project Research Assistant [100% FTE]. The Research Assistant will provide support to the investigators and the Project Manager on aspects related to the research conducted at the various sites. The Research Assistant will assist with data management, creation of reports, etc., and will work directly with the Node Research Coordinators to ensure completeness and accuracy of data, including managing data query tracking and reports.

Taryn Mayes, M.S., Network Administrator [20% FTE]. Ms. Mayes is the Center Manager for the Center for Depression Research and Clinical Care. Ms. Mayes has over 20 years of research experience in pediatric psychopharmacological and psychosocial intervention trials for depression and suicide and has been responsible for the supervision of research staff, training, assessment fidelity, regulatory oversight, and data management on many research studies. Over the past several years, she has provided oversight to the research and clinical programs conducted within the Center. Ms. Mayes will assist with protocol development, provide oversight on budget and study administration, and provide supervision to the Administrative Associate, Accountant, and Human Resource Associate.

TBD, Regulatory Manager [50% FTE]. The Regulatory Manager will provide oversight of regulatory requirements for UT Southwestern and all Nodes and Sites and will ensure Node

Investigators and Coordinators adhere to regulatory requirements across the institutions. The Regulatory Manager will travel to the Nodes to conduct monitoring visits, which will include a review of regulatory and participant data files.

Sahayog Thapa, Senior Accountant [20%]. Mr. Thapa will oversee study funding and ensure fiscal accountability and will oversee the disbursement and reporting of funds for all Nodes and the overall network.

Ericka Hardman, Administrative Associate [75%]. Ms. Hardman will serve as the Administrative Associate for the Network. Her responsibilities will include completing all necessary purchases and travel arrangements for the project, scheduling Network meetings for Dr. Trivedi and Dr. Hughes, taking minutes for the Node Investigator meetings, distributing meeting minutes and other materials, and assisting Dr. Trivedi with Node communications.

Robyn King, Human Resource Associate [20%]. Ms. King will coordinate all aspects of Human Resource administration for UT Southwestern, including hiring, onboarding, terminations, personal and sick leave, appraisals, and other personnel related activities.

Jonathan Zimmerman, Database Architect [100%]. Mr. Zimmerman will be the lead data management and analytics for the project. He has served as the lead Data Analyst for a large international multi-site study. Mr. Zimmerman will develop the database system, user interface, and data query system for the entire project, and will also be responsible for creating reports for the nodes and overall network. Mr. Zimmerman will be responsible for programming the electronic data capture (EDC) system in the first year of the project, and for maintaining the EDC throughout the study, including implementation of upgrades and any changes needed. He will implement the data management procedures and facilitate the overall data acquisitions and locked database in the final year, under Dr. Minhajuddin's direction. Mr. Zimmerman will ensure that the data dictionary and annotated case report forms are provided to study investigators for use in the development of analyses of study outcomes. He will also provide data pulls and reports for ongoing quality control reports and audits, including the development of an ongoing weekly monitoring system that is designed to insure completeness and accuracy of data. Additionally, he will pull data for DSMB reports and any other ongoing system reports as needed.

Tianyi Wang, Data Manager [100%]. Ms. Wang will assist in the development of the database and user interface, and will manage all aspects of data, including data checking, data cleaning, and working with the Nodes and sites to ensure accuracy and completeness of data. She will also provide training around data entry and data queries for all investigators and coordinators. Additionally, she will pull data for DSMB reports and any other ongoing system reports as needed.

Travel:

Travel costs include a Network launch meeting for the full team and funds for the Faculty Project Manager, Senior Research Site Managers, and Regulatory Manager to visit nodes.

Equipment:

A data server will be purchased in Year 1 to manage the large volume of data obtained during the study.

Software: N/A

Contracts:

TCMHCC Centralized Child Depression Website Development

We are requesting funds for the development and maintenance of the Network website, which will include updates, research information, and educational materials. The website will be available to the public but will also include a secure site for Node and Research Site personnel to access important study information and reports. The majority of the costs will be associated with website development, and will occur in Year 1, with additional funds requested in Year 2 for maintaining and updating the site and reporting tools.

TCMHCC Child Depression Network Database and Reporting Systems Development

We are requesting funds for the development and maintenance of the database and reporting systems, including planning, development, implementation, and maintenance of the database and reporting system, as well as necessary licensing fees. Critical components of a Data Management solution and related processes include:

- Defining the requirements of the study data
- Designing of databases and case report forms
- Determining the most feasible data entry process
- Developing a data dictionary
- Providing access and permissions to documents and data for all users (Nodes and Sites)
- Collecting and storing participant details and study data
- Ensuring quality control and assurance of data
- Developing and implementing data archiving and destruction processes
- Providing data access permissions for analysis ready data
- Building data interfaces for integration into Business Intelligence products
- Developing Business Intelligence data visualizations

The HUB will manage all aspects of data management for the Network. All study data will be collected through TCMHCC Research Electronic Data Capture (EDC) System – a self-managed, secure, web-based software solution designed to support data collection strategies for clinical research studies. The EDC system software helps researchers quickly develop databases for collecting and managing research data. All of the Nodes and Sites participating in the study will have permission to submit validated data forms and receive feedback, alerts, or notifications from the EDC system as well as receiving reports and validation queries using secure transmission technology.

The HUB leadership has worked with excellent database developers on previous projects, and we will obtain bids from these and other developers for the proposed project. The selected company will have experience in developing secure data-driven solutions, developing interfaces into Business Intelligence software, and developing back-end systems and client side web-based systems using state of art technologies and practices, all of which will be included in the scope of the TCMHCC Database development for the project. The selected company will have

experience in developing a large rapid response system in Microsoft based technologies, primarily SQL Server and C-Sharp (C#), Angular 8+, non-relational databases, Business Intelligence interfaces and dashboards and certifications in SQL, Microsoft and Sales Force software systems.

TCMHCC Child Depression Network Training Materials and Videos

We are requesting funds for the development and production of training materials to be used across all Nodes and recruitment sites. Dr. Trombello will develop professionally created training videos, as well as binders with materials for users to refer to during the study. The majority of the training materials will be developed in Year 1, with additional funds requested in Year 2 for maintaining and updating the documents.

Materials:

Computer

Funds are requested for three IBM compatible computers and monitors to be purchased in Year 1 for the Senior Research Site Managers and Project Research Assistant. The computers will be for word processing, data and subject tracking, data management, production of mailing labels, e-mail communication, correspondence with nodes and participants, preparation of IRB and other regulatory forms, as well as preparation and dissemination of research findings. Computers for all other study personnel are already supplied by UTSW.

iPads

Funds are requested for two iPads for the project team to allow for flexible completion of work-related activities, particularly during travel and meetings.

Study Materials

We are requesting funds for study supplies to be used in this project, including data drives, general office supplies, statistical software, and materials to compile study binders.

Informational Materials

We are requesting funds for the development and production of informational materials to be used across all Nodes. Materials will be electronic and physical copies for recruitment of study sites, study participants, and psychoeducation. The majority of the Informational Materials will be created in Year 1, with funds in Year 2 for production of additional materials.

Conference Calls

Funds are requested for conference call expenses. During Year 1, we anticipate several calls and an increased number of callers as the study is developed and sites are selected. In addition, we will have weekly conference calls for all Nodes throughout the course of the study.

Server Maintenance

Server maintenance for the study server.

Texas Child Mental Health Care Consortium Research

Title of the Research: Child Trauma Research Network

Co-PIs: Charles B. Nemeroff, MD, PhD and Karen Wagner MD, PhD

1. What is the overall purpose of the study?

The purpose of the study is to identify the mental health outcomes of acute and chronic trauma for children and adolescents, identify risk and protective factors, and identify best practices to improve the mental health of children and adolescents in Texas who have experienced trauma.

2. What are the objectives? List each objective separately.

1. Identify the mental health outcomes of acute trauma (e.g. abuse, assault, serious accident, serious medical emergency, death of parent, COVID-19 pandemic) and chronic trauma (e.g. bullying, domestic violence, sexual abuse and neglect) for children and adolescents.
2. Identify the risk factors that lead to negative mental health outcomes (posttraumatic stress disorder, depression, anxiety disorders, alcohol and substance use disorders) for children and adolescents who have experienced trauma.
3. Identify the protective factors that lead to positive mental health outcomes for children and adolescents who have experienced trauma.
4. Identify interventions that improve the mental health outcomes for children and adolescents who have experienced trauma.

3. How does the study address current gaps in services?

The devastating consequences of exposure to traumatic experiences in childhood, including child abuse and neglect, is extremely well documented, beginning with the classic Adverse Childhood Experiences (ACE) studies funded by the CDC and several subsequent follow up studies. It is now well established that childhood maltreatment is extremely common with more than 4 million reported cases in the United States yearly, and these numbers do not include trauma associated with automobile accidents, other forms of physical injury and medical emergencies. Texas has 10% of all the children in the United States. In 2019 there were >294,000 reports of child abuse and neglect in our state and 235 child fatalities attributed to abuse and neglect. Statewide, approximately 730,000 children and youth (1 in 10 overall) report 3 or more adverse childhood experiences and almost 90,000 children have been exposed to 10 or more such adverse experiences. Four of ten families were re-reported for abuse/neglect in 5 years since the initial investigation. There were >70,000 children who were victims of Human Sexual Trafficking in Texas last year. Child abuse and neglect results in a marked increase in vulnerability to serious psychiatric and medical disorders, resulting ultimately in a markedly shorter life span. Thus, childhood maltreatment increases the prevalence rate and severity of depression, anxiety disorders including post-traumatic stress disorder (PTSD), alcohol and substance use disorder, as well as asthma, heart disease, stroke, obesity, diabetes and certain

forms of cancer. Children who are victims of abuse and neglect exhibit poorer school performance and employment as adults, and higher rates of incarceration. These devastating effects are even more prominent in certain special populations including children of color, children living in poverty, and LGBT status.

There is limited information about the mental health outcomes of children and adolescents who have experienced acute and chronic trauma. This study will provide needed clinical information in order to address the mental health needs of children and adolescents who have experienced trauma.

There is limited information about risk factors that predict worse mental health outcomes and protective factors that improve mental health outcomes for children and adolescents who have experienced trauma. This study will identify those risk and protective factors so that children and adolescents that have experienced trauma may have improved mental and physical health.

There is limited information about interventions to treat children and adolescents who have experienced trauma. This study will provide information about a variety of interventions that may improve the mental health of children and adolescents who have experienced trauma.

4. In 5-years,

How can you foresee this research can inform clinical practices?

- Clinicians will know what mental health disorders are likely to occur for children and adolescents who have experienced trauma so that clinicians can intervene early and provide needed treatment to improve outcomes.
- Knowledge of risk factors that predict negative mental health outcomes will enable clinicians to identify those children and adolescents who will need intensive treatment
- Knowledge of protective factors will enable clinicians to incorporate this information in the treatment plan for children and adolescents who have experienced trauma.
- Clinicians will be informed about clinical interventions that lead to positive mental health outcomes for children and adolescents who have experienced trauma.

How could it inform public policy?

- Minimize those risk factors that lead to negative mental health outcomes for children and adolescents who have experienced trauma
- Promote protective factors that lead to positive mental health outcomes for children and adolescents who have experienced trauma
- Implement interventions shown to improve mental health outcomes for children and adolescent who have experienced trauma

5. List the methods which will be used to achieving this research

The childhood trauma network consisting of researchers from academic Departments of Psychiatry will participate in this research. Children and adolescents who have experienced acute or chronic trauma will be evaluated and have follow-up over the course of a year to determine mental health outcomes. Recruitment sites include trauma centers, emergency departments, hospitals, pediatric, primary care and mental health clinics, and advocacy centers.

6. What types of data that would be collected for this research?

Demographic data, psychiatric history, medical history, family medical and psychiatric history, and psychiatric and psychological assessments.

7. How will the data be secured?

A Childhood Trauma Network secure database will be developed and maintained for confidential reporting of subject data from the nodes to the hub. All study data will be collected through TCMHCC Secure HIPPA Compliant Research Electronic Data Capture (EDC) System, a self-managed, secure, web-based software solution designed to support data collection strategies for clinical research studies. All of the nodes will submit validated data forms and receive feedback, alert or notifications from the EDC system using secure transmission technology.

8. How will people impacted by this issue be incorporated in the design and implementation of the protocols?

Family and youth engagement experts from the Hogg Foundation for Mental Health, Texas Institute for Excellence in Mental Health, and Texas HHSC have been invited to participate in the trauma research network planning calls. These engagement experts will input into the final protocol design and enable the network to connect with youth and family members.

9. What types of information would be provided as a result of this research?

- The information from this research will be presented at state and national meetings, in publications, in position statements and policy recommendations.
- The data from this study will enable submissions to NIMH and other agencies for further research in this area.
- The State of Texas will be informed about the mental health needs and recommended interventions for children and adolescents who have experienced trauma.

10. How do you see that data/information utilized by:

Researchers in Texas.

- The establishment of this state trauma network will form the foundation for multiple NIH grant applications from investigators at all the node sites.

- Further research collaboration within the childhood trauma network
- Presentations at state and national meetings
- Publications in scientific and lay publications

Clinicians

- Increase knowledge about the mental health course of children and adolescents who have experienced trauma
- Intervene early when children and adolescents have experienced trauma
- Incorporate protective factors in treatment planning
- Utilize interventions that are likely to improve the mental health outcomes of children and adolescents who have experienced trauma

Policy Makers

- Recommend direction for future mental health research funding for children and adolescents who have experienced trauma
- Recommend strategies to address the mental health needs of children and adolescents who have experienced trauma more effectively and efficiently.
- Identify treatment pathways that result in improved child welfare outcomes, including improved safety, improved permanency outcomes because children and families receive effective care, and improved wellness outcomes, including school retention and performance and employment outcomes
- Better treatment outcomes due to trauma informed care more broadly in the mental health school and mental health systems including school retention and performance and employment outcomes.

HUB Details:

a) What is the role of the HUB in the research?

The role of the HUB is to support the 11 nodes and enable them to carry out the work of subject recruitment and data collection. As such the HUB personnel will train each of the node sites on precisely how to collect the subject data step by step. This will be accomplished by in person visits to the node sites on a regular basis. Once the data is obtained, it is available to all members of the network for data analysis and generation of publications. The HUB will provide the statistical expertise to enable the node faculty/investigators and members of the TCMHCC executive committee to query the data base to address important issues in the trauma field.

b) List activities of the HUB.

The primary responsibilities of the HUB include designing the protocol (in collaboration with the node members and other interested parties), establishing the parameters of assessment schedules,

selection of measurement tools, developing forms, establishing monitoring parameters and supervising all of the node activities. The HUB is solely responsible for the data management and will oversee preparation of progress reports as required.

More specifically, The HUB is responsible for:

- Training researchers in the use of the measurement tools, forms and monitoring procedures
- Carrying out ongoing monitoring and coaching
- Convening node research leads in regular monitoring calls (weekly at first, tapering to monthly by year two)
- Carrying out core data analysis on behalf of the network for augmentation by hub and node researchers
- Coordinating additions/changes to the protocol over time as needed
- Convening a coordinating committee to oversee research design ongoing
- Coordinating and monitoring of federal grants that emanate from the network. This includes helping develop federal grant proposals
- Mentoring junior faculty from the nodes and helping them with submission of new federal grants
- Extending the opportunity for node researchers to participate in multi-site federal grants

c) List the proposed key staff for the HUB.

Faculty

Charles Nemeroff, MD, PhD – Network Scientific Lead

Karen Wagner, MD, PhD – Network Co-Lead (UTMB)

Nate Kimbrel, PhD – Faculty Project Manager

Mark Bond, PhD – Assistant Professor/Statistician

Jeff Shahidullah, PhD – Psychology Training Lead

Carol Tamminga, MD – TCMHCC Research Chair

Justin Rousseau, MD – Database Architect

Staff

Ashleigh Smith, LCSW – Senior Research Site Manager

Lisa Jackson, JD, RN – Network Administrator

Wade Weber – Data Manager

TBD – Senior Research Site Manager

TBD – Regulatory Manager

Faculty:

Charles B. Nemeroff, Network Scientific Lead. Dr. Nemeroff is Professor and Chair of the Department of Psychiatry, and Director of the Institute for Early Life Adversity Research. He has extensive experience in the implementation of clinical trials and the evaluation of factors that influence disease development and course, as well as treatment response, for depressive disorders. He has served as PI on many major NIH Funded multi-site grants that include both academic and real-world clinical practice centers and has demonstrated success in collaborating with a broad range of clinicians and investigators.

Dr. Nemeroff's responsibilities in the proposed study include designing the protocol, establishing the parameters of assessment schedules, selection of measurement tools, developing forms, establishing monitoring parameters and supervising the faculty and staff of the Network Hub, as well as the TCMHCC Data Management Center (including data collection, management, and coordination). He will ensure that project goals are met in a timely manner with integrity, that the work is done within budgeted amounts and is in compliance with University requirements, that participant recruitment progresses on schedule, and that data are collected and analyzed properly. Dr. Nemeroff will visit each of the Nodes regularly and ad hoc when needed. He will also hold biweekly All Node calls with Dr. Wagner to discuss the progress of the program and address safety and recruitment concerns. Dr. Nemeroff assumes responsibility for health and safety standards and protection of Human Subjects. He will also provide oversight leading and coordinating the Childhood Trauma Network in all aspects of study implementation, preparation and submission of progress reports, management of study funding, and will work with the node leads and members of the TCMHCC research committee in preparation of manuscripts to disseminate study results. He will continue to engage and sustain performance at all Nodes and work with Dr. Wagner, all Node Leads, the Research Workgroup of the TCMHCC and be responsible for reporting back to the Executive Committee of the TCMHCC. He will also ensure continued consensus around all aspects of the study implementation.

Karen Wagner, MD, PhD, Network Medical Co-Lead. Dr. Wagner is Chair of the Department of Psychiatry and one of the leaders of child psychiatry in the United States. She has been the principal investigator of many clinical research studies in children. Dr. Wagner will serve as the Co-Lead for the project. Dr. Wagner will provide leadership and work with Dr. Nemeroff to ensure implementation of the research protocol and will also provide advice to Nodes with Dr. Nemeroff ensuring that all the Hub procedures are executed as planned.

Nate Kimbrel, Ph.D., Faculty Project Manager [60% FTE]. Dr. Kimbrel is an Associate Professor of Psychiatry, and has extensive experience working with children and adolescents with depression and suicidal behaviors, as well as in the trauma field. He has extensive clinical research experience with multiple previous large scale federally funded projects. Dr. Kimbrell will be responsible for coordinating the day-to-day operations of the Network, directly supervising the HUB research coordinator, Ashleigh Smith. He will work with all Node Investigators and Sites to ensure successful implementation of the research projects implemented across the network. He will assist with the operational management of the trial, especially day-to-day management of start-up, study operations and procedures. He will assist with monitoring activities related to start-up, ongoing implementation, and study closure are occurring, and oversee personnel associated with the research infrastructure. He will provide guidance to regional infrastructure Node leadership, as well

as regional Node staff. He will guide protocol implementation and assist with training and resolution of day-to-day issues related to the functioning and consistent implementation of the study. He will work with Nodes on recruiting sites, training, and study implementation. He will develop training materials and monitor quality of assessments at each node. He will assist Dr. Nemeroff with communications to Node leadership. He will also assist the Leads in dissemination efforts associated with the project. During the project start-up, Dr. Kimbrel will travel to each Node to work with investigators and study coordinators to provide training and to develop potential partner clinics. He and Dr. Trivedi will also visit each Node regularly and ad hoc when needed.

Mark Bond, Ph.D., Statistician [75% FTE]. Dr. Bond is an Assistant Professor in the Department of Psychiatry. He has extensive experience with statistical analyses and data. Dr. Bond will have primary responsibility for establishing the data base and conducting all analyses of outcomes and will oversee the data management process. He will provide expertise and development of novel analytical approaches to the study of large and complex datasets and will also provide guidance on data management and contribute to study manuscripts. He will assist in writing manuscripts and progress reports.

Jeff Shahidullah, Ph.D., Psychologist Training Lead [30% FTE]. Dr. Shahidullah is an Assistant Professor in the Department of Psychiatry. Dr. Shahidullah will develop the training program for the Network and will conduct training workshops and individual training opportunities to investigators and research staff, as well as provide ongoing rating calibrations and re-certifications.

Justin Rousseau, M.D., TCMHCC Trauma Database Architect [20%]. Dr. Rousseau is the co-director of the Data Core at Dell Medical School, where he leads a centralized team to support access, integration and the use of data to affect health. He will oversee the development of the database system, user interface, and data query system for the project, and will oversee the creation of reports for the nodes and overall network. He will implement the data management procedures and facilitate the overall data acquisitions. He will also provide data pulls and reports for ongoing quality control reports and audits, including the development of an ongoing weekly monitoring system that is designed to insure completeness and accuracy of data. Additionally, he will pull data for DSMB reports and any other ongoing system reports as needed.

Other Staff:

Ashleigh Smith, LCSW Senior Research Site Manager [65% FTE]. Ms. Smith has several years conducting clinical research and has served as a coordinator over several collaborative research studies involving multiple sites. She will serve as one of the two Senior Research Site Managers. The Senior Research Site Managers will each be responsible for half of the Nodes. They will ensure that all project deliverables are met in a timely manner and will be responsible for coordinating the Nodes to ensure ease of study implementation, participant recruitment, and data collection. In addition, the Senior Research Site Managers will be responsible for developing reports and other ongoing communications across the Nodes and with the state, and will assist with regulatory requirements, including managing the UT Austin IRB for this project. They will hold primary responsibility for organization of all meetings and associated tasks and data collection/analyses to be completed in between meetings and will work with Drs. Kimbrel and Shahidullah to provide oversight and implementation of the Node site and Data Management Center. In addition, they will travel to their respective Nodes to provide training to Node Research Coordinators and will conduct regularly scheduled visits to each Node to review recruitment and data integrity. They will also hold

weekly calls with the Node Research Coordinators to review recruitment progress, protocol changes, and data management issues.

TBD, Senior Research Site Manager [100% FTE]. The Senior Research Site Manager will serve as one of the two Senior Research Site Managers and will be responsible for half of the Nodes.

TBD, Project Research Assistant [100% FTE]. The Research Assistant will provide support to the investigators and the Project Manager on aspects related to the research conducted at the various sites. The Research Assistant will assist with data management, creation of reports, etc., and will work directly with the Node Research Coordinators to ensure completeness and accuracy of data, including managing data query tracking and reports.

Lisa Jackson, J.D., R.N. Network Administrator [20% FTE]. Ms. Jackson is the Executive Director of the Office of Research at Dell Medical School. Ms. Jackson has over 20 years of leadership experience in clinical and translational research. She is responsible for the supervision of research staff, training, assessment fidelity, regulatory oversight, and data management on many research studies. Ms. Jackson will provide oversight on budget and study administration.

TBD, Regulatory Manager [50% FTE]. The Regulatory Manager will provide oversight of regulatory requirements for DellMed and all Nodes and Sites and will ensure Node Investigators and Coordinators adhere to regulatory requirements across the institutions. The Regulatory Manager will travel to the Nodes to conduct monitoring visits, which will include a review of regulatory and participant data files.

Jan Thornton, Senior Accountant [20%]. Ms. Thornton will oversee study funding and ensure fiscal accountability and will oversee the disbursement and reporting of funds for all Nodes and the overall network.

TBD, Administrative Associate [75%]. We will hire an Administrative Associate for the Network. The associate's responsibilities will include completing all necessary purchases and travel arrangements for the project, scheduling Network meetings for Dr. Nemeroff and Dr. Kimbrel, taking minutes for the Node Investigator meetings, distributing meeting minutes and other materials, and assisting Dr. Nemeroff with Node communications.

Kathryn Flowers, Human Resource Associate [20%]. Ms. Flowers will coordinate all aspects of Human Resource administration for DellMed, including hiring, onboarding, terminations, personal and sick leave, appraisals, and other personnel related activities.

Wade Weber, Data Manager [75%]. Mr. Weber will assist in the development of the database and user interface, and will manage all aspects of data, including data checking, data cleaning, and working with the Nodes and sites to ensure accuracy and completeness of data. He will also provide training around data entry and data queries for all investigators and coordinators. Additionally, he will pull data for DSMB reports and any other ongoing system reports as needed.

Fringe: A 30% fringe rate is applied to faculty and staff salaries.

Travel

Travel costs include a Network launch meeting for the full team and funds for the Faculty Project Manager, Senior Research Site Managers, and Regulatory Manager to visit nodes.

Equipment A data server will be purchased in Year 1 to manage the large volume of data obtained during the study.

Software: N/A

Contracts

TCMHCC Centralized Child Trauma Website for Data Capture development

We are requesting funds for the development and maintenance of the Network website, which will include updates, research information, and educational materials. The website will be available to the public but will also include a secure site for Node and Research Site personnel to access important study information and reports. The majority of the costs will be associated with website development, and will occur in Year 1, with additional funds requested in Year 2 for maintaining and updating the site and reporting tools.

TCMHCC Child Trauma Network Database and Reporting Systems Development

We are requesting funds for the development and maintenance of the database and reporting systems, including planning, development, implementation, and maintenance of the database and reporting system, as well as necessary licensing fees. Critical components of a Data Management solution and related processes include:

- Defining the requirements of the study data
- Designing of databases and case report forms
- Determining the most feasible data entry process
- Developing a data dictionary
- Providing access and permissions to documents and data for all users (Nodes and Sites)
- Collecting and storing participant details and study data
- Ensuring quality control and assurance of data
- Developing and implementing data archiving and destruction processes

- Providing data access permissions for analysis ready data
- Building data interfaces for integration into Business Intelligence products
- Developing Business Intelligence data visualizations

The Hub will manage all aspects of data management for the Network. All study data will be collected through TCMHCC Secure HIPAA Compliant Research Electronic Data Capture (EDC) System – a self-managed, secure, web-based software solution designed to support data collection strategies for clinical research studies. The EDC system software helps researchers quickly develop databases for collecting and managing research data. All of the Nodes and Sites participating in the study will have permission to submit validated data forms and receive feedback, alerts, or notifications from the EDC system as well as receiving reports and validation queries using secure transmission technology.

The Hub will obtain bids for the proposed project. The selected company will have experience in developing data-driven solutions, developing interfaces into Business Intelligence software, and developing back-end systems and client side web-based systems using state of art technologies and practices, all of which will be included in the scope of the Database development for the project. The selected company will have experience in developing a large rapid response systems in Microsoft based technologies, primarily SQL Server and C-Sharp (C#), Angular 8+, non-relational databases, Business Intelligence interfaces and dashboards and certifications in SQL, Microsoft and Sales Force software systems.

Training Videos

We are requesting funds for the development and production of training materials to be used across all Nodes and recruitment sites. Dr. Shahidullah will oversee the creation of professionally created training videos, as well as binders with materials for users to refer to during the study. The majority of the training materials will be developed in Year 1, with additional funds requested in Year 2 for maintaining and updating the documents.

Materials

Computer

Funds are requested for three IBM compatible computers and monitors to be purchased in Year 1 for the Senior Research Site Managers and Project Research Assistant. The computers will be for word processing, data and subject tracking, data management, production of mailing labels, e-mail communication, correspondence with nodes and participants, preparation of IRB and other regulatory forms, as well as preparation and dissemination of research findings. Computers for all other study personnel are already supplied by DellMed.

iPads

Funds are requested for two iPads for the project team to allow for flexible completion of work-related activities, particularly during travel and meetings.

Study Materials

drives, general office supplies, statistical software, and materials to compile study binders.

Informational Materials

We are requesting funds for the development and production of informational materials to be used across all Nodes. Materials will be electronic and physical copies for recruitment of study sites, study participants, and psychoeducation. The majority of the Informational Materials will be created in Year 1, with funds in Year 2 for production of additional materials.

TEXAS RESEARCH NETWORKS

Childhood Trauma
Depression/Suicide

TCMHCC Research Workgroup

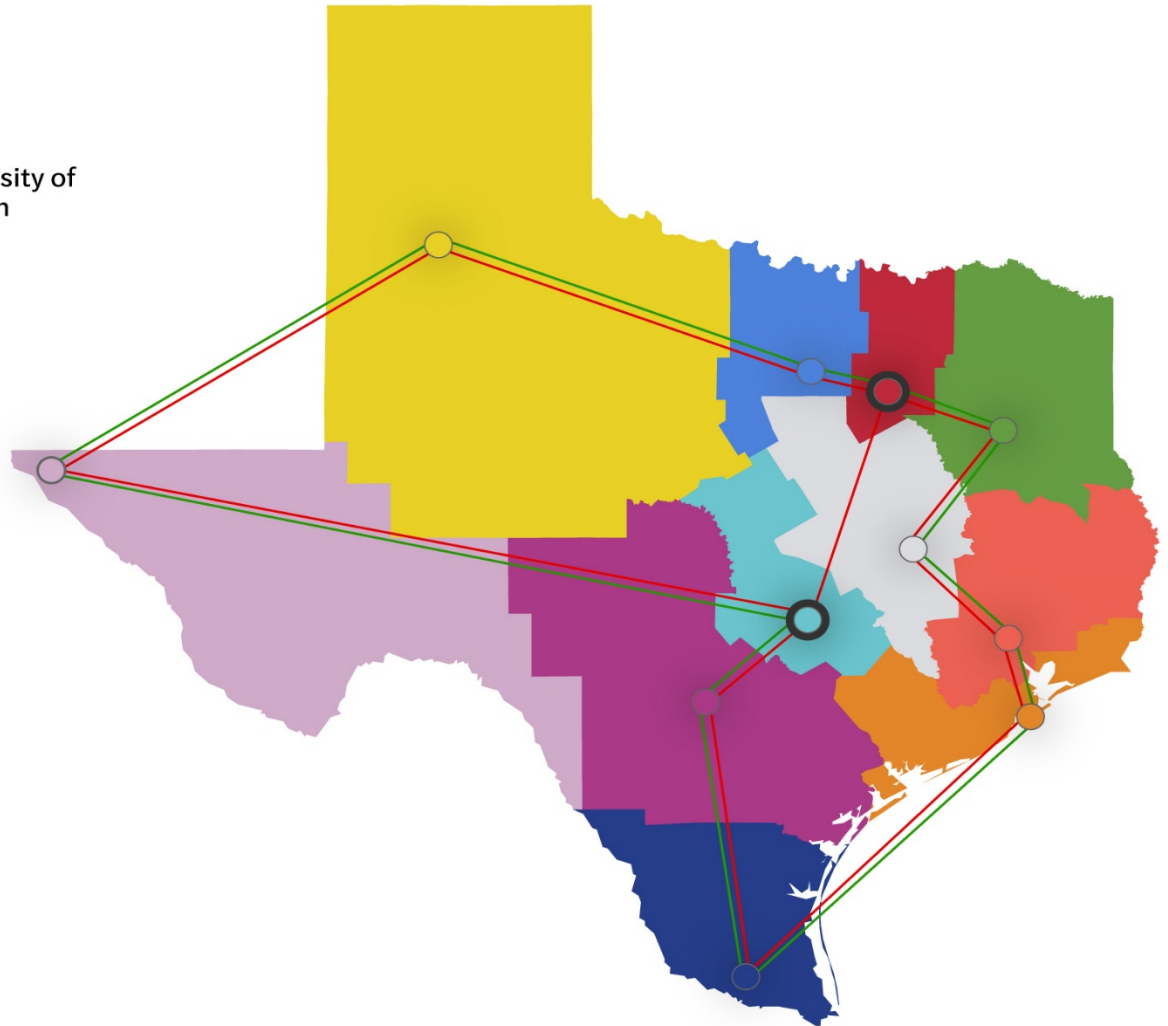
Carol A. Tamminga, Chair

What is the overall purpose of the TCMHCC Research study?

- The initial purpose is to create Texas-wide research Networks as 'Learning Healthcare Networks' across all of the 12 Texas HRIs in Child Psychiatry.
- The second purpose of this study is to improve the evaluation of and response to the increasing problem of (i) youth depression and suicide and (ii) trauma-informed care in Texas by coordinating 'learning' in a research network of Health-Related Institutions across the state.

TEXAS RESEARCH NETWORKS

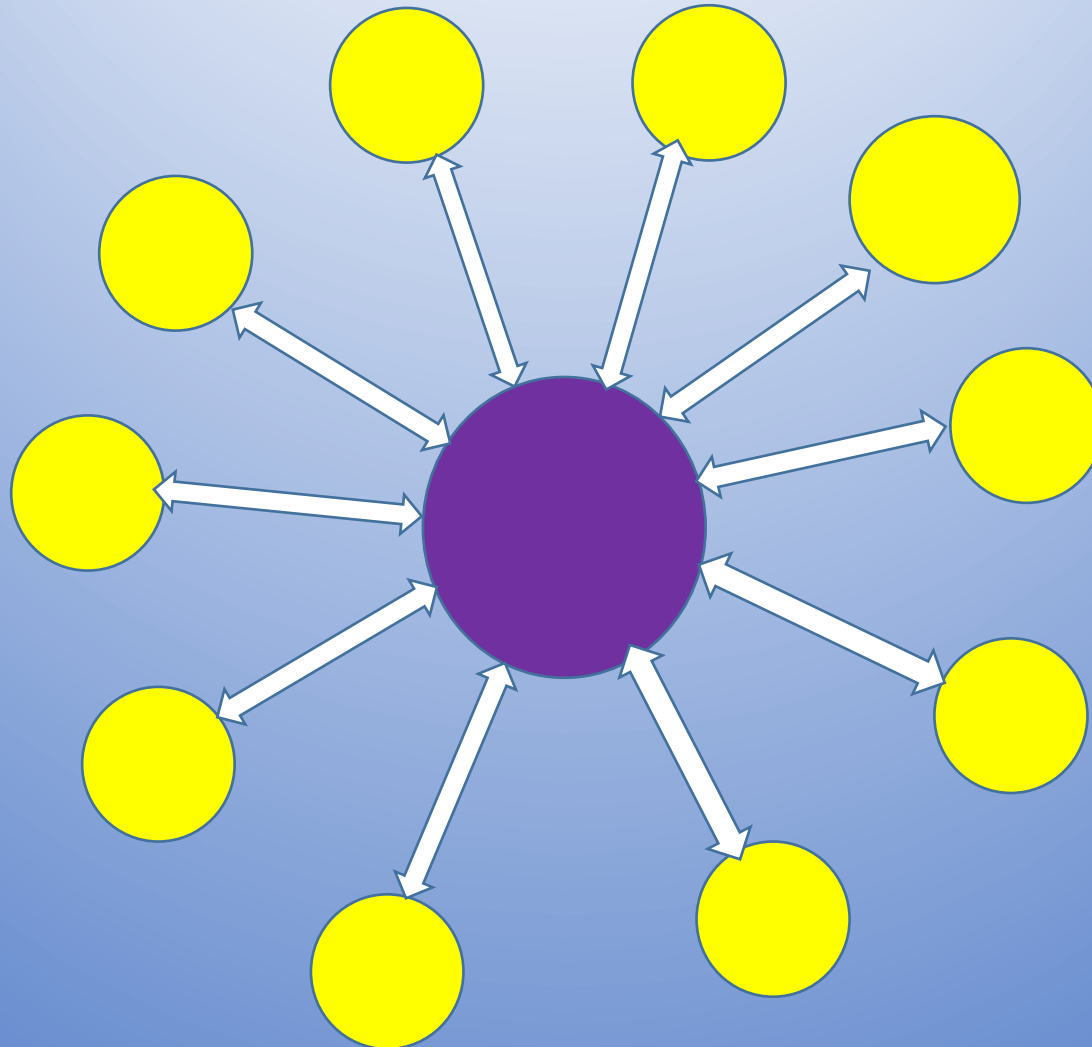
- Texas A&M University System Health Science Center
- Baylor College of Medicine | The University of Texas Health Science Center at Houston
- Dell Medical School at The University of Texas at Austin
- The University of Texas Southwestern Medical Center
- Texas Tech University Health Sciences Center at El Paso
- Texas Tech University Health Sciences Center
- The University of Texas Health Science Center at Tyler
- University of North Texas Health Science Center
- The University of Texas Medical Branch at Galveston
- The University of Texas Rio Grande Valley School of Medicine
- The University of Texas Health Science Center at San Antonio



How does the study address current gaps in services?

- Many Texas communities lack the resources and infrastructure for early detection and evidence-based treatment in trauma and depression.
- Gaps exist in knowledge related to trauma consequences and depression effects as related to individual risk and resilience.
- Most Texas HRIs have strong research that can be stronger – and more successful in attracting federal funding – if we work together.
- Some HRIs in Texas who focus primarily on clinical care want to develop a significant research infrastructure.
- This research will provide informative clinical models for short and long-term outcomes associated with youth trauma, depression and suicide and will identify regionally specific and state-wide service delivery gaps to inform the targets for policy makers and legislators to improve health care of youth in Texas.

Network Structure: Hub and Node Model



Two Networks: Childhood Trauma and Depression/Suicide

HUB Responsibilities

- Primary responsibility for the soundness of the research and its execution across the Network.
- Work closely with Hub and Node faculty to generate publications emanating from the network.
- Mentor junior faculty together with Node leadership
- Help establish research recruitment strategies to yield at least 1000 subjects
- Train on diagnostic and rating scales
- Establish cross-site reliability
- Create regular Network communication
- Set up the Data Base with RedCap for data capture and analysis with local access

Node Responsibilities

- Scientific collaborators in the Network research, based on their expertise
- Lead authors on their research, co-authors on other research in which they participate
- Subject recruitment, as able, to ensure diverse and representative sampling
- Perform the baseline workup as specified
- Follow the child over time, specific to each Network project, for up to 12 months
- Enter clinical data into the RedCap system
- The Network Data Base belongs to the Network and is best used when each site works up a piece of the data for distribution

Childhood Trauma Network Protocol

Measure	Baseline	One Month	Six Months	Twelve Months
MINI-KID	X		X	X
TESI-C	X			
TESI-P	X			
PCL-5	X	X	X	X
ISRC	X			
CRAFFT & NIDA Screen	X	X	X	X
SCARED-C	X	X	X	X
SCARED-P	X	X	X	X
CHRT-SR	X	X	X	X
CD-RISC	X			
EIS	X			
SAS-School Scale	X	X	X	X

Scale	Measure Of	Completed By		No. Items	Est Mins
		Child	Parent		
MINI Intl. Neuropsychiatric Interview (MINI-KID)	Diagnosis	Child			15-50
Traumatic Events Screening Inventory (TESI-C)	Traumatic Event(s)	Child	Parent	24	20-30
Immediate Stress Reaction Checklist (ISRC)	Trauma Reaction	Child		27	10
PTSD Checklist for DSM-5 (PCL5)	PTSD symptoms	Child		20	5-10
Patient Health Questionnaire for Adolescents (PHQ-A)	Depression	Child		9	5
Screen for Child Anxiety Related Disorders (SCARED)	Anxiety	Child	Parent	41	10-15
CRAFFT & NIDA/NIAAA Screener Questions	Drugs / Alcohol	Child		8	5
Concise Health Risk Tracking – Self Report (CHRT-SR)	Suicidality	Child		7	5
Connor-Davidson Resilience Scale (CD-RISC)	Resilience	Child		25	5-10
Social Adjustment Scale-School scale	School performance	Child		7	5
Ethnic Identity Scale (EIS)	Cultural Identity	Child		17	5
				Total	90-150

Childhood Depression/Suicide Network Protocols

	Clinic Screening	Clinic Baseline	Monthly Remote Surveys	Timing Depends on Clinic and MBC						Research Phone Visits (3 months)
				Clinic V 2	Clinic V 3	Clinic V 4	Clinic V 5	Clinic V 6	Clinic Follow-up Visits	
Measures										
PHQ-A	X	X	X	X	X	X	X	X	X	
CHRT-SR	X	X	X	X	X	X	X	X	X	
GAD-7	X	X	X	X	X	X	X	X	X	
MINI-KID		X								X (only at 12 month)
CHRT-C		X								X
SCARED		X	X							
TESI		X								X (only at 12 month)
CRAFFT		X	X	X	X	X	X	X	X	
PROMIS-29		X	X	X	X	X	X	X	X	
SAS-School		X	X	X	X	X	X	X	X	
SDQ		X	X							
CD-RISC		X	X							
EIS		X								
Accountable Health Communities Screening Tool		X						X	X	
CASA		X						X	X	X
BACE		X						X	X	X
FIBSER-Child		X		X	X	X	X	X	X	
CAST		X		X	X	X	X	X	X	
PAQ-R		X		X	X	X	X	X	X	
Demographics		X								
FHS		X								
** Additional Measures to be Added as Approved										

TCMHCC RESEARCH BUDGET: HUB AND NODES, 2020/2021

Health Related Institution	Childhood Depression/Suicide	Childhood Trauma	FY2020 - Childhood Depression/Suicide	FY2020 - Childhood Trauma	FY2020 - Both Research Projects	FY2021 - Childhood Depression/Suicide	FY2021 - Childhood Trauma	FY2021 - Both Research Projects	FY20-21 Childhood Depression/Suicide	FY20-21 Childhood Trauma	FY2020-FY2021 Both Research Projects
HUB/lead/co-lead	UTSW/TTU	UTDell/UTMB	\$688,725	\$692,832	\$1,381,557	\$1,343,082	\$1,393,423	\$ 2,736,505	\$2,031,807	\$2,086,256	\$4,118,063
Baylor	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTMB	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
TAMUHSC	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UT Dell	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
TTUHSC	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTHSC Houston	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTHSC SA	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTRGV	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTSW	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
TTUHSC El Paso	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
UTHSC Tyler	X	X	\$250,000		\$ 250,000	\$250,000		\$ 250,000	\$500,000		\$ 500,000
Total	11	11	\$2,750,000		#####	\$2,750,000		#####	\$5,500,000	\$ -	\$9,618,062

Research Networks

Dr. Trivedi/Dr. Wakefield Depression/Suicide

- BSM/ Dr. Storch
- UTMB/ Dr. Defilippis
- TAMUHSC/ Dr. Streusand
- UTDell/ Dr. Koli
- TTUHSC/ Dr. Kahathuduwa
- UTHSCH/ Dr. Soares
- UTHSCSA/ Dr. Garza
- UTRGV/ Dr. Escamilla
- UTSW/ Dr. Kennard
- UTHSCTy/ Dr. Idell

Dr. Nemeroff/Dr. Wagner Trauma

- BSM/ Dr. Schneider
- UTMB/ Dr. Shotwell
- TAMUHSC/ Dr. Liberzon
- UTDell/ Dr. Talebi
- TTUHSC/ Dr. Gomez
- UTHSCH/ Dr. Taylor
- UTHSCSA/ Dr. Garrett
- UTRGV/ Dr. Escamilla
- UTSW/ Dr. Stewart
- UTHSCT/ Dr. Wherry

TCMHCC RESEARCH WORKGROUP

Carol Tamminga

Joseph Blader

Michael Escamilla

Andy Keller

Israel Liberzon

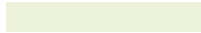
Charles Nemeroff

Jair Soares

Eric Storch

Texas Child Mental Health Care Consortium DRAFT Research Initiative budget

Health Related Institution	Childhood Depression/Suicide	Childhood Trauma	FY2020 - Childhood Depression/Suicide	FY2020 - Childhood Trauma	FY2020 - Both Research Projects	FY2021 - Childhood Depression/Suicide	FY2021 - Childhood Trauma	FY2021 - Both Research Projects	FY20-21 Childhood Depression/Suicide	FY20-21 Childhood Trauma	FY2020-FY2021 Both Research Projects
HUB/lead/co-lead	UTSW/TTU	UTDell/UTMB	\$688,725	\$692,832	\$1,381,557	\$1,343,082	\$1,393,423	\$ 2,736,505	\$2,031,807	\$ 2,086,256	\$4,118,063
Baylor	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTMB	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
TAMUHSC	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UT Dell	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
TTUHSC	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTHSC Houston	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTHSC SA	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTRGV	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTSW	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
TTUHSC El Paso	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
UTHSC Tyler	X	X	\$250,000	\$ 250,000	\$250,000	\$250,000	\$ 250,000	\$ 250,000	\$500,000	\$ 500,000	\$ 500,000
Total	11	11	\$2,750,000	\$4,131,557	\$2,750,000	\$2,750,000	\$5,486,505	\$5,500,000	\$ -	\$ 9,618,062	



Youth Depression & Suicide Research Network

A Research Initiative of the Texas Child Mental Health Care Consortium
[\(https://www.utsystem.edu/pophealth/tcmhcc/\)](https://www.utsystem.edu/pophealth/tcmhcc/)

Protocol Version 1.0

Madhukar H. Trivedi, M.D. (UT Southwestern Medical Center)

Sarah Mallard Wakefield, MD (TTUHSC)

SB11 Youth Depression & Suicide Research Network:

The following have enrolled to participate as Nodes with Node leaders

1. Baylor College of Medicine-Eric Storch, PhD
2. UTMB-Melissa DeFilippis, MD
3. TAMU-Israel Liberzon, MD, William Streusand, MD
4. UT Dell Austin-Roshni Koli, MD
5. TTUHSC-Chanaka Kahathuduwa, MD, PhD
6. UTHSC Houston-Jair Soares, MD, PhD
7. UT Health San Antonio-Joe Blader, PhD
8. UT Rio Grande Valley-Michael Escamilla, MD
9. UT-Southwestern-Betsy Kennard, PsyD
10. TTUHSC El Paso-Sarah Martin, MD
11. UT Tyler-Richard Idell, MD
12. UNTHSC-TBD

Childhood Trauma Network- Dr. Charles Nemeroff

State Health And Human Services Advisors: Sonja Gaines and Mike Maples

Introduction and Background

Depression and suicide in youth are devastating and critical public health problems, and both are on the rise in the United States. Rates of past year major depressive episodes increased 52% between 2005 and 2017 (from .1% to 13.2%) among adolescents (Twenge et al., 2019). Additionally, suicide is now the second leading cause of death in persons aged 10-24 in the United States. A recent CDC report focused on this age group highlighted that after a stable trend in suicide rates from 2000 to 2007, the rate sharply increased from 2007 (6.8 per 100,000 persons) to 2017 (10.6 per 100,000 persons; Curtin et al., 2019).

Youth depression is a life altering illness, given that it is burdensome, often chronic, and disabling. About one in 11 children experience some form of depression before the age of 14, and the risk of major depressive disorder (MDD) doubles from late childhood to early adolescence. Large population surveys estimate between 11-18% of youth will experience a depressive disorder by age 18 (Avenevoli et al., 2015). Within any given year, about 13% of youth meet diagnostic criteria for depression or another mood disorder, with some studies suggesting that 66-75% of all lifetime depressive diagnoses begin during adolescence (Hankin et al., 2015; NIMH, 2017). Depressed youth have been shown to have negative cognitive functioning, including increased cognitive distortions, negative attributions, hopelessness, and low self-esteem, school difficulties, social impairment, poorer family relationships, and even substance abuse problems (AACAP, 2007). Most (approximately 90%) children and adolescents recover from an initial episode of MDD within 1-2 years of onset (AACAP, 2007); however, any time spent depressed during this important time of development is impairing. While most do recover, subsequent episodes of depression are common, with 50-60% of youth experiencing a relapse of depression (AACAP, 2007; Emslie et al., 2008; Kennard et al., 2009, 2014). Because adolescence is a critical period for brain development and the development of social skills/networks, undetected and untreated depression has far-reaching consequences for educational, social-emotional, and economic outcomes in adulthood. The CDC estimates that mental illnesses among children result in an annual cost of \$247 billion due to their impact not only on children, but on families and communities (Perou et al., 2013).

Depression and suicide impact a significant number of Texas youth. Specifically, among youth aged 13-17 in Texas, the 12-month prevalence rates are estimated to be 160,877 for depression and 186,382 for self-injury or self-harming behaviors. According to the 2017 Youth Risk Behavior Survey Texas data brief, 34.2% of Texas high school youth report feeling so sad or hopeless almost daily for 2 or more weeks that they stopped doing some usual activities in the past year (Texas Department of State Health Services, 2018). Additionally, 17.8% of Texas high school youth reported having serious thoughts about suicide, 14.5% made a plan, 12.3% attempted suicide, and 4.5% reported having made a suicide attempt that required medical attention in the past 12 months. Even more striking, Texas high school students had a 66% higher rate of attempted suicide in the past year than those in the U.S. (12.3% in Texas vs. 7.4% in US overall, based on the 2017 Youth Risk Behavior Survey data).

Table 1 compares the 12-month prevalence rates of depression and suicidal behaviors for Texas and the United States (U.S. Department of Health and Human Services, 2018). Furthermore, Mental Health of America ranks states according to prevalence of mental illness and access to care. Texas ranks last among the U.S. states for access to mental healthcare (Mental Health America, 2020).

Table 1. Rates of depression and suicidal behaviors in youth

Texas Adolescent Mental Health

Texas

United States

Percent of students who report they felt sad or hopeless almost every day for 2 or more weeks in a row so that they stopped doing some usual activities (during the 12 months before the survey)	34%	31%
Percent of adolescents ages 12-17 who report they had at least 1 major depressive episode (during the 12 months before the survey)	12%	13%
Percent of students who report they seriously considered attempting suicide (during the 12 months before the survey)	18%	17%
Percent of students who report they attempted suicide 1 or more times (during the 12 months before the survey)	12%	7%
Percent of students who report they attempted suicide resulting in an injury, poisoning, or overdose that had to be treated by a doctor or nurse (during the 12 months before the survey)	5%	2%

* Data adapted from HHS.gov based on 2017 data (<https://www.hhs.gov/ash/oah/facts-and-stats/national-and-state-data-sheets/adolescent-mental-health-fact-sheets/texas/index.html>)

Advances in psychological science as well as intervention and services research have resulted in a number of treatment and service delivery strategies with documented benefits for improving outcomes for youth and families (Asarnow et al., 2015). The problem is not that youth depression and suicide cannot be sufficiently prevented or alleviated in most cases, but that communities lack the education, resources and infrastructure needed for early detection and evidence-based treatment. Many pediatric providers remain reticent to treat mental health concerns, leading to inconsistent identification and treatment of depression (Wissow et al., 2017). It is estimated that approximately 60% of pediatric patients with mental health concerns receive no treatment. Many of the remaining 40% likely receive inadequate treatment, given the documented differences in treating pediatric populations, lack of access to evidence-based therapies, and provider hesitancy to treat with medications.

In 2016, the U.S. Preventive Services Task Force recommended screening for major depressive disorder for adolescents aged 12-18 years of age (UTSPSTF, 2016). Despite improved outcomes through the adoption of universal screening, the consistent use of measurement-based care, as well as the utilization of collaborative care models in pediatric settings, the current status of depression is similar to that of cardiovascular disease in the 20th century. Substantial gaps exist about the clinical, functional, behavioral, social and biological mechanisms of depressive disorders as related to an individual’s risk of developing depression, ability to cultivate resilience, and response to treatment. This inadequate understanding of the trajectory of the disorder over a lifetime, in addition to the accompanying stigma associated with the disease, significantly impedes prevention. It is essential to identify risk markers, indicators of onset, long-term (natural) course of disease, and treatment-associated outcomes.

The Texas Child Mental Health Care Consortium (TCMHCC) was generously funded by the Texas legislature in 2019. The opportunity to carry out health services research in child mental health was an extension of the clinical care opportunities for children and both are now being overseen by the Executive Committee (EC) of TCMHCC. The goal of the research component in TCMHCC is to examine highly impactful research areas in child mental health, where great need exists and where we think health services research can make a significant contribution to child mental health care in areas aligned to the state-wide Behavioral Health Strategic Plan.

The “Learning Healthcare System” approach to health services research will be our model (IOM, National Academies Press, Wash DC, 2007). The research will have to directly address needs in child mental health as they exist in Texas and will have to improve systems of care in the state. The research will have to focus on health priorities; have powerful outcomes; be evidence-based; be built on existing research where it exists; and be available to all HRIs; and it will be a bonus if the research can lead to additional federal or voluntary research funding. The questions asked in this research will have to be important and impactful, as well as advance care for children in Texas.

Study Aims:

- **Develop a patient registry to describe population health outcomes for youth with depression and/or suicidal ideation or behavior**
- **Characterize and support measurement-based care (MBC) and collaborative care coordination in participating clinics**
- **Develop predictive models for short- and long-term outcomes**

Building the Network

All 12-13 sites represented in SB11 have been invited to participate in the Youth Depression and Suicide Research Network as “Nodes.” Each Node has obtained support of senior institutional leadership including the department chair. Leadership from each Node provided input and edits in the study design process by committee, with a focus on the inclusion of the “end user” in design decisions. Nodes must have the patient volume to be able to recruit at least 500 to 750 patients over the course of 1.5 years, and they will be required to work closely with Network leadership to recruit, monitor, and retain participants. This will require active engagement and sustained relationships with clinics within the academic medical center as well as clinics in the community (i.e., psychiatry, psychology, counselling).

Study Design

Overview: Nodes will identify leadership and staff to manage the study in each region. Nodes will develop partnerships with primary care, pediatric, specialty care, and/or community clinics to implement the study. Once all Nodes and clinic sites have been identified and training is completed, the Youth Depression and Suicide Network will launch. Nodes/sites will refer youth and parents to the Patient Registry, where data will be collected as described. Additionally, participating clinic sites will be monitored for universal screening and use of MBC and collaborative care, with metrics collected for each aim. The wealth of data collected through the Network’s patient registry will help scientists better understand disease development in young people, resulting in the development of practical tools that may be translated back into clinical and community-based settings: predictive models for risk and treatment optimization. A risk index allows for the assignment of individual risk based on a combination of factors (i.e., those showing elevated symptoms, those who have recovered from acute episodes of depression or substance use), which can translate into an estimate of the individual’s probability of developing the disorder or experiencing a relapse. Treatment optimization models that predict the optimal treatment method for individuals who have developed depression can augment clinician judgment and perhaps reduce the physical, emotional, and financial burden associated with the typical trial-and-error treatment approach. The models will be externally validated in real-time as data from more participants are collected, with the most efficacious model chosen on the basis of its ability to perform well when applied to new participants. Our goal is to identify the strongest clinical predictors – both short-term (12 weeks) and long-term (9-12 months). These predictive models will inform future research and allow clinicians, educators, and other youth-related stakeholders to provide more informed education and treatment recommendations to youth, parents, and families who present with risk factors for depression.

Design:

Youth patients of participating clinics (ages 8-20) who screen positive for depression or suicidality (defined as suicidal ideation or behavior), and their parents will be recruited for participation in the Network Registry Study. Upon informed consent/assent, baseline data will be collected regarding mood symptoms, suicidal ideation and behavior, associated comorbidities, treatment history, services use, and social determinants of health. Youth participants and parents will be sent monthly measures through the Electronic Data Capture (EDC) system developed and maintained by UT Southwestern. Additionally, measures will be given at provider visits to support delivery of measurement-based care within the clinics.

Methods:

Screening, Informed Consent, and Study Enrollment. At each site, clinics will screen all youth with the 2-item PHQ-2 through a computer or tablet. A description of the study and e-consent form will be presented to the youth and parent during the screening process. Youth who screen positive and receive treatment for depression or suicidality will be flagged in the system to alert research personnel. The research coordinator will meet with the youth and parent, obtain informed consent/assent to proceed, and instigate the EDC system surveys, which must be completed within 7 days of screening.

Enrollment/Randomization/Completion of Baseline Measures. The research staff will document the patient's eligibility and willingness to participate using the EDC system and ask the participant to complete baseline measures.

Monthly Remote Assessments. In order to collect longer-term, real-world, naturalistic outcome data, youth participants and parents will be asked to complete monthly assessments online using our established EDC system. Participants will be prompted to complete the patient-centered outcome questionnaires on a monthly basis for a total of 12 months or the end of the biennium. The following measures will be collected monthly via the remote capture EDC: 1) Patient Health Questionnaire 9-item (PHQ-A), 2) measure of suicidal ideation and behavior (CHRT), 3) measures of social and school function – the Patient Reported Outcomes Measurement Information System (PROMIS)-29 and the Social Adjustment Scale – School scale, 4) Generalized Anxiety Disorder – 7 (GAD-7).

Post-Baseline Clinic Visits and Assessments. All symptom severity and functioning measures will be collected at each visit using the EDC system. While in-person clinic visits will be left to discretion of the clinic, providers will be strongly encouraged to bring in youth being treated with an antidepressant and or psychotherapy more frequently during initial stages of treatment, consistent with guidelines. In addition, providers will obtain side effect measures – the Frequency, Intensity, and Burden of Side Effects Rating (FIBSER) scale and the Concise Associated Symptom Tracking Self-Report (CAST), and a medication adherence measure – the Patient Adherence Questionnaire (PAQ). If EDC is not available or not preferred for individual participants, we will provide paper copies of the validated scales that can be entered into the EDC by research personnel.

Study Schedule

	Clinic Screening	Clinic Baseline	Monthly Remote Surveys	Timing Depends on Clinic and MBC						Research Phone Visits (3 months)
				Clinic V 2	Clinic V 3	Clinic V 4	Clinic V 5	Clinic V 6	Clinic Follow-up Visits	
Measures										
PHQ-A	X	X	X	X	X	X	X	X	X	
CHRT-SR	X	X	X	X	X	X	X	X	X	
GAD-7	X	X	X	X	X	X	X	X	X	
MINI-KID		X								X (only at 12 month)
CHRT-C		X								X
SCARED		X	X							
TESI		X								X (only at 12 month)
CRAFFT		X	X	X	X	X	X	X	X	
PROMIS-29		X	X	X	X	X	X	X	X	
SAS-School		X	X	X	X	X	X	X	X	
SDQ		X	X							
CD-RISC		X	X							
EIS		X								
Accountable Health Communities Screening Tool		X						X	X	
CASA		X						X	X	X
BACE		X						X	X	X
FIBSER-Child		X		X	X	X	X	X	X	
CAST		X		X	X	X	X	X	X	
PAQ-R		X		X	X	X	X	X	X	
Demographics		X								
FHS		X								
** Additional Measures to be Added as Approved										

Study Population

This study will enroll youth with depression and/or suicidal ideation. In addition to youth with depression, we will proactively identify a youth population presenting with suicidal behavior. To improve generalizability, the study will use broad inclusion and minimum exclusion criteria, which are detailed below.

Eligibility Criteria. We have chosen minimal eligibility criteria for the proposed project to ensure that the screening process can be implemented in the healthcare settings with minimal disruption to existing clinic workflow. Inclusion criteria: 1) age 8-20 years, 2) positive screen for depression (e.g., based on PHQ-2 (score ≥ 3) and/or PHQ-A of 10 or greater, OR positive for suicidal ideation or behavior (e.g., based on CHRT-SR or PHQ-A item 9); 3) parents and youth willing to provide consent/assent, respectively. Exclusion criteria: 1) Inability of patient and/or family to dedicate appropriate time to complete scheduled study assessments and measures, 2)

medical or psychological condition(s) that would result in an inability to accurately complete study requirements (e.g., neurological conditions or significant neurodevelopmental concerns), 3) active psychotic symptoms, 4) parent deemed cognitively unable to provide consent, and 5) inability to provide a reliable means of contact. Patients eligible will be representative of major races and ethnicities.

Study Assessments Measures

Measure	Domain	Completed By	Number of Items	Estimated Completion Time (minutes)
MINI-KID	Diagnostic Interview	Assessor (interview with youth and parent)	n/a	15-60
PHQ-A	Depressive symptoms	Youth	9	5
PHQ-A-Parent Completed	Child's depressive symptoms	Parent	9	5
CHRT-C	Suicidal ideation and behavior	Assessor (interview with youth and parent)	9	5-15
CHRT-SR	Suicidal ideation, behavior, risk	Youth	16	5-10
GAD-7	Anxiety screener	Youth	7	5
SCARED-Child	Anxiety symptoms	Youth	41	10-15
SCARED-Parent	Child's anxiety symptoms	Parent	41	10-15
TESI-C	Traumatic Event(s)	Assessor (interview with youth and parent)	n/a	10-30
CRAFFT	Substance Use and Impairment	Youth	8	5
PROMIS-29-Pediatric	Functioning	Youth	29	15
PROMIS-29-Parent Proxy	Functioning	Parent	29	15
SAS - School scale	School Functioning	Youth	6	5
SDQ-SR	Prosocial and problem behaviors	Youth	25	15
SDQ-P	Prosocial and problem behaviors	Parent	25	15
CD-RISC	Resilience	Youth	25	5-10

EIS	Cultural identity	Youth	17	5
Accountable Health Communities Screening Tool	Social determinants of health	Parent	10	5
CASA	Mental health services utilization	Assessor (interview with youth and parent)	10	15
BACE	Barriers to Care	Parent	30	15
FIBSER-Child	Medication side effects	Youth	3	<1 (only if on medication)
CAST	Antidepressant treatment-emergent symptoms	Youth	17	10 (only if on medication)
PAQ-R	Medication adherence	Youth	2	<1 (only if on medication)
Demographics Form	Demographics related to youth, parents, and family	Youth and Parent	TBD	5
FHS	Family History	Parent	7	5
ABCD Study Measures				

Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI-KID). The MINI-KID is a short, structured diagnostic interview for DSM-V and ICD-10 psychiatric disorders in children and adolescents.

Patient Health Questionnaire-A (PHQ-A). The PHQ-A is a nine-item, self-report inventory that assesses for symptoms in all nine symptom domains of a major depressive episode. It is the PHQ-9 modified for adolescents 11-18 years. Parents will also complete this measure about their child's symptoms.

Concise Health Risk Tracking Scale (CHRT), Clinician-Rated (CHRT-C) and Self-Report (CHRT-SR). The CHRT is a scale that evaluates specific thoughts about suicide and thoughts and feelings associated with an increased risk for suicide.

Generalized Anxiety Disorder Scale – 7 items (GAD-7). The GAD-7 is self-report that assesses for symptoms in 7 symptom domains of generalized anxiety, with an additional question on anxiety-related functional impairment. We have successfully used this measure in participants as young as age 10.

Screen for Child Anxiety Related Disorders (SCARED)- Child and Parent Versions. The SCARED is a 41-item inventory to screen for signs of anxiety disorders in children.

Traumatic Events Screening Inventory (TESI). The TESI is an interview that assesses a child's experience of potential traumatic events, including current and previous injuries, hospitalizations, domestic violence, community violence, disasters, accidents, physical abuse, and sexual abuse. The TESI-C is for use with individuals aged 6-18.

CRAFFT Screening Tool (CRAFFT). The CRAFFT is used to screen for substance-related risk and problems in youth, with the acronym corresponding to the six domains of functional impairment associated with substance use and related problems (Car, Relax, Forget,

Friends, Trouble).

Patient Reported Outcomes Measurement Information System (PROMIS)-29 Pediatric/Parent Proxy. The PROMIS-29 consists of 29 self-reported items rated on a 5-point Likert scale. The PROMIS-29 provides scores on global health as well as sub-scores in three domains: physical health, mental health, and social health. The PROMIS-29 items have demonstrated acceptable reliability and validity. Given feedback from pediatric partners, we recently reviewed the PROMIS to include a Pediatric/Parent Proxy version with adapted language for youth/parents.

Social Adjustment Scale – School Module. The SAS-School Module consists of 6 items to measure school functioning and performance.

Strengths and Difficulties Questionnaire (SDQ). The SDQ is a 25-item measure of positive and negative attribute in youth, including emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behavior. The measure includes a self-report version for those aged 11-16, and a parent or teacher version to rate youth aged 4-16.

Connor-Davidson Resilience Scale (CD-RISC). The CD-RISC is a 25-item measure of resilience, or adaptability, in youth.

Ethnic Identity Scale (EIS). The EIS is a 17-item measure that assesses three components of ethnic-racial identity (exploration, resolution, and affirmation).

Accountable Health Communities Screening Tool. The Accountable Health Communities Screening Tool is a 10-item measure designed by the Centers for Medicare and Medicaid (CMS) to assess patient needs in 5 domains related to social determinants of health: housing instability, food insecurity, transportation difficulties, utility assistance needs, and interpersonal safety.

Child and Adolescent Services Assessment (CASA). The CASA is a self-and parent-report instrument designed to assess the use of mental health services utilization by children ages 8 - 18. We will add items to assess type of psychotherapy received (e.g., CBT, IPT, family therapy).

Barriers to Access to Care Evaluation Scale (BACE). The BACE is a 30-item self-administered scale designed to assess barriers to mental health care for people with mental health problems. It includes barriers related to, and unrelated to, stigma and discrimination. It contains a 12-item subscale, which measures the extent to which stigma and discrimination are barriers to care ('treatment stigma').

Frequency, Intensity, and Burden of Side Effects Rating (FIBSER) -Child. The FIBSER is a 3-item scale that asks participants to rate the frequency, intensity and burden of side effects on a 7-point Likert scale. The FIBSER has been shown to be a reliable and valid (significant correlations with Patient Rated Inventory of Side Effects and FIBSER score was predictive of discontinuing treatment in STAR*D) measure for assessing side effects. Given feedback from pediatric partners, we recently reviewed the FIBSER-C with adapted language for youth.

Concise Associated Symptom Tracking Self-Report (CAST). The CAST is a 17-item inventory that assesses for five known antidepressant treatment-emergent symptom domains: irritability, anxiety, mania, insomnia, and panic.

Patient Adherence Questionnaire - Revised (PAQ-R). This 2-item self-report questionnaire of adherence asks about the number of days' antidepressant medications were either missed or changed in the past 7 days.

Demographics Form. The Demographics form includes questions about 1) the youth's age, sex, gender identity, sexual orientation, education level, race and ethnicity; 2) the parents' marital status, employment status, and education levels; and 3) the family's income level and current zip code.

Family History Screen (FHS). The FHS is a self-report completed by parents, assessing for family history of depression, anxiety, bipolar disorder, suicide, schizophrenia, alcohol abuse, and other psychiatric disorders.

Node and Clinic Level Procedures

Developing Partnerships

Formal site selection criteria will be developed by the study team, so that selected sites are as comparable as possible, while still providing generalizability. The proposed study's regions offer a wide and heterogeneous assortment of clinic types in terms of clinic models, approaches to behavioral health, provider type, clinic size, payment models, and patient demographics. Identified sites/areas serve significant underprivileged and underserved populations that will enrich subgroup analyses and generalizability of the study.

The formal site selection process for clinics will begin with Nodes providing information about the proposed study and gathering information about the clinics' current practices around treating youth depression and suicide. Through that process, clinics may express interest in serving as a clinic performance site. Once selected, clinics will commit to: 1) supporting recruitment efforts for the study, including providing physical space where research personnel can confidentially conduct consenting, screening, and assessment visits; 2) identifying a site "champion" that will serve as the primary liaison between clinic personnel and research staff; 3) collaborate with Node and Youth Depression and Suicide Research Network leadership, as well as local study staff, to keep informed about the study; 4) work with study staff to integrate research activities into the clinic, with consideration of minimal disruption to clinic activities; 5) work with study staff to ensure that study procedures are conducted in line with regulations and approvals set forth by the UT Southwestern Institutional Review Board, HIPAA authorizations, and data use authorizations.

The process of clinic selection and partnership will be similar to what Dr. Trivedi has used as part of the Center for Depression Research and Clinical Care (CDRC) partnerships with community providers through the VitalSign6 program.

Measurement-Based Care

Given the "Learning Healthcare System" approach, this research will both evaluate the healthcare systems' screening and monitoring of youth systems, but will also aim to improve systems of care in the state. This project aims to enhance the utilization of MBC in all participating clinics. Data will be obtained about the participating clinics' use of MBC guidelines at study initiation and throughout the duration of the site's participation in the Network. Sample questions include type of behavioral healthcare model utilized (e.g., referral-based care, integrated care, collaborative care), use of depression and suicide screening measures, use of follow-up depression and suicide measures, frequency of follow-up measures, and access to evidence-based therapy providers (e.g., CBT or IPT). Training in MBC will be included in site initiation visits, with additional educational opportunities offered throughout the project.

MBC guides recommendations for treatment of depression in primary care, and may include pharmacotherapy, psychotherapy, or a combination of both. Depressed patients treated in primary care clinics have similar outcomes to those in psychiatric settings when identical systematic measurement-based care (MBC) procedures are followed. The MBC approach includes (1) standardized assessment of symptoms, side effects, and treatment adherence; (2) point-of-care decision-making for treatment; (3) consistent follow-up visits; and (4) feedback to clinicians to assist decision making. Use of MBC is associated with rates of remission twice as high when compared with standard of care and has now been adopted in treatment guidelines

for depression. As clinicians rarely administer serial measurements in their practice, the MBC approach relies on patient self-report assessments for both screening and management of depression.

Collaborative Care

For selected clinics who have a Collaborative Care model or who chose to develop a Collaborative Care model during the course of this research, additional data will be obtained on the site's implementation and treatment practices for participants (e.g. number of contacts, type and duration of therapy, etc.). Collaborative Care is an integrated care model that has been shown to improve patient outcomes, save money, and reduce stigma related to mental health (University of Washington, 2013). This model involves the integration of care managers and consultant psychiatrists, with primary care physician oversight, to more proactively manage mental illnesses. Collaborative care focuses on defined patient populations tracked in a registry, measurement-based practice and treatment to target. Trained primary care providers and embedded behavioral health professionals provide evidence-based medication or psychosocial treatments, supported by regular psychiatric case consultation and treatment adjustment for patients who are not improving as expected. Consistent with the adult literature, our review of the existing literature with children and adolescents supports the value of integrated care models where behavioral health care is available through primary care services, with particularly strong results for collaborative care models that deliver team-based care (Asarnow, Rozenman, Wiblin, & Zeltzer, 2015).

Prevention and Management of Suicidal Behavior

We have established methods for assessing risk and developing safety plans. Participants who are at risk of suicide attempts may need to be psychiatrically hospitalized. We collaborate with clinic partners to follow the procedures of the AACAP Practice Parameters on Suicidal Behavior. These parameters indicate that participants should be referred for hospitalization if their condition is unstable—as manifested by, suicidal ideation with inability to contract for safety, psychosis, current intoxication, mania, rapid cycling, or mixed state. Social factors that may cause the clinician to consider hospitalization include lack of sufficient environmental support and structure to guarantee the child's safety. We will provide the patient and family with emergency contact numbers if there is imminent risk. If upon follow-up, participants are not in treatment and we identify serious psychopathology and/or suicidal risk, we will provide referral information to the participant and parents. If at any of these points, we perceive that the patient is in imminent suicidal risk and the parent/patient is not willing to address this issue, then we will contact emergency mental health services to initiate a commitment. These steps will be done in collaboration with partnering clinics and collaborative care providers.

Node Training, Engagement, and Quality Assurance

Nodes and clinic sites within each node will receive training on engaging youth and families in Patient Registry participation. Clinic sites within each node will be required to provide evidence-based depression care for youth, which includes the adoption of universal screening, measurement-based care, and the utilization of the collaborative care model. Measurement-based care (MBC) for the treatment of depression includes the systematic assessment of symptoms, treatment side effects and adherence at defined intervals using research-validated self-report instruments.

The Network's lead team, in collaboration with Node leadership, will offer educational and consultation opportunities for partnering clinics to enhance engagement. Additionally, clinic-level data on MBC outcomes will be provided in reports and dashboards to enhance engagement and to provide real-time feedback on use of MBC processes.

Data Management System

A Data Management Plan will be developed by UT Southwestern. Research data management includes the:

- Definition of required study data
- Design of databases and case report forms
- Data entry process
- Development of a data dictionary
- Access and permissions to documents and data
- Collection and storage of participant details and study data
- Quality control and assurance of data
- Data archiving and destruction
- Data access permissions for analysis ready data

Data will be collected through TCHMCC Research Electronic Data Capture (EDC) System – a self-managed, secure, web-based software solution designed to support data collection strategies for clinical research studies. The EDC system software helps researchers quickly develop databases for collecting and managing research data. All of the sites participating in the study will have permission to submit validated data forms and receive feedback, alerts, or notifications from the EDC system as well as receiving reports and validation queries using secure transmission technology.

Statistical Analyses

The goals of the statistical analyses is primarily two-fold: a) to provide a descriptive summary of the data by participating network nodes as well as by various socio-demographic characteristics of the participants such as age groups, gender (as a biological variable), urban or rural, degree of fidelity to MBC, etc.; and b) to build predictive models for treatment outcomes and trajectories of disease course as well as models to assist with treatment selection that may benefit subgroups of participants. Treatment outcomes of interest are remission defined as alleviation of illness and response defined as reduction in disease burden. For example, at a fixed pre-determined visit (e.g., 3 months) a participant will be considered to be in remission for depression if the PHQ-9 total score is below a predetermined threshold, while a participant will be considered to be in response if there is at least 50% reduction in depressive symptoms as measured by the PHQ-9 from their baseline levels. Participant's clinical characteristics at baseline as well as early changes in some clinical measurements will be used as predictors.

Since this is not a randomized controlled trial (RCT), these predictive models will be adjusted for socio-demographic characteristics of participants to control for differences in these features. Additionally, the diversity in the types of participants in terms of gender, race, ethnicity, rural versus urban setting for caregiving, regions of the state, types of care such as MBC or MBC+ will be included in the predictive models to illustrate potential effects of these on the treatment outcomes. Thus, this study cohort provides a unique opportunity to incorporate effects of a large number of socio-demographic characteristics as well as caregiving scenarios on treatment outcomes such as remission and response. These predictive models can therefore help policy makers to focus their attention to specific regions or socio-demographic sub-groups of participants, if needed.

On regular pre-specified intervals (e.g., every three or six months), the data will be summarized using various descriptive statistics such as mean and standard deviations or median and inter-quartile range for continuous variables and frequency and percentages for the categorical

characteristics. These summaries will be provided for the study as a whole as well as for each participating nodes. They will also be segregated by various participant characteristics of interest such as age group, gender, race, ethnicity, urban versus rural, social determinants of health, degree of fidelity to MBC, etc.

Predictive modeling will utilize a number of statistical approaches to build parsimonious models for outcomes of interest such as remission and response. Multivariable logistic regression models will be estimated to predict likelihood of remission or response based on baseline clinical variables as well as early changes in these clinical measurements. In brief, logistic regression analysis models the log-odds of the outcome (remission or response) as a function of a set of candidate predictor variables. The models will be adjusted for differences in participant's socio-demographic characteristics to account for any variability in the outcome due to differences in these socio-demographic characteristics. To identify a more parsimonious model, statistical variable selection methods such as backward and/or stepwise selection will be utilized. Odds ratios and their 95% confidence interval will be reported to describe how a candidate predictor influences the likelihood of the outcome of interest.

A second approach to build predictive models for outcomes will utilize covariance-regularized logistic regression models. This technique is useful when the number of potential predictors is large compared to number of participants available to estimate such a model, and also when there is substantial collinearity between predictors. Examples of such techniques is the Least Absolute Shrinkage and Selection Operator (LASSO) method proposed by Tibshirani (1996) or it's more general version Elastic net proposed by Zou et al. (2005). The advantage of these techniques is that the variable selection is built into the model estimation methods and thus model building process is simplified and the resulting models are easier to interpret by researchers.

To assess model stability, statistical methods such as 10-fold cross-validation will be utilized where the available data will be randomly split into 10 groups and the data from the 9 of the 10 groups will be used to estimate the model and then the resulting model will be used to predict outcomes for participants in the 10th groups. The process will be repeated 10 times, each time leaving a different 1/10th group out and ultimately classifying the full sample following the scheme. The stability for the full sample model will be assessed by comparing full sample model predictions with those from the cross-validated predictions. These methods will be used to develop scales using the results of the models to predict future remissions, the time it will take for a 50% reduction of severity, non-responders, and future risk of suicide. Additionally, these models will be validated using independent data collected from the nodes at a later but similar time interval.

To identify if a certain treatment modality is optimal for a sub-group of participants, recursive partitioning methods will be used. This relative treatment effectiveness varying over subgroups comes down to a treatment-subgroup interaction and identification of such interactions is crucial for personalized medicine and optimal treatment assignment strategies (Tunis et al, 2010; Dehejia, 2005). Recursive partitioning is a statistical technique that allows identification of such a treatment-subgroup interaction to identify sub-groups of participants who are more (or less) likely to remit or respond under certain treatment modality. Baseline socio-demographic and clinical characteristics will be used as candidate risk-variables. This approach develops a decision tree which selects treatment and baseline characteristics which maximize the sensitivity and specificity of the decision tree in prediction of treatment response, while minimizing complexity. There are multiple statistical methods to develop a decision tree using recursive partitioning. Examples are a) model-based recursive partitioning (Zeileis et al., 2008),

b) interaction trees (Su et al., 2008, 2009), c) simultaneous threshold interaction modeling algorithm (STIMA; Dusseldorp et al., 2010), d) subgroup identification based on differential effect search (SIDES; Lipkovich et al., 2011), and e) virtual twins (Foster et al., 2011). For the current application, model-based recursive partitioning will be utilized to identify and build a decision tree with an optimal, fixed number of terminal nodes (sub-groups) representing complex interactions between treatment modality and baseline characteristics. This decision tree will then be used to identify a nominal categorical variable that will be used in a logistic regression model with treatment response as the outcome and this newly created nominal variable as the only independent variable in the model. Additionally, this nominal sub-group identifier will be used in an analyses of variance model with treatment modality as the second factor and clinical measurement of interest at a pre-specified follow-up time point as the outcome to estimate a standardized measure of the effect of the interactions.

Ethical Considerations

Risk/Benefit Assessment

Potential Risks. Participants must be capable of understanding the nature of this study, its potential risks, discomforts and benefits, which will be presented through an informed consent/assent process to youth and parent(s)/guardian(s)/legally authorized representative(s). Study staff will obtain consent after they have fully explained the study purpose and its procedures, and potential participants have demonstrated an understanding of the protocol, willingness to participate, and competency to consent. Youth participants will be under the care of their provider, who will be responsible for treatment selection, informed consent, and monitoring.

Confidentiality and Loss of Privacy. The risk of loss of privacy is judged to be low. However, patients will be asked to provide personal identifying information at each site, and there is a very rare risk of breach of confidentiality.

Planned Procedures for Protecting Against or Minimizing Potential Risks

Breach of confidentiality: Risk of breach of confidentiality will be minimized by the following measures: 1) personal identifying information (i.e. name on informed consent, data of birth) will be recorded on a paper source, will be cross-referenced with a de-identified participant number, and will be stored in a separate binder and this binder will be locked in a file cabinet. De-identified data will then be coded and entered into password-protected databases on password-protected and encrypted computers in locked offices. Data will be shared and analyzed in a de-identified manner only. For the Network Registry Study, only de-identified information will be entered.

Risks not specific to interventions received through clinical provider: Close monitoring of participants throughout the study will ensure that adverse effects from treatment, exacerbation of symptoms, or emergence of suicidality, mania or psychosis will be promptly recognized so that providers can treat appropriately. All participants will be instructed on how to contact their clinical provider in the case of an emergency. They will also be instructed on how to contact emergency mental health services serving their clinic which provide emergent psychiatry care on a 24 hour/day basis.

Clinical Monitoring of Participants and Safety Considerations. All patients will receive monitoring for clinical deterioration, support, attention, and reassurance in the context of a therapeutic alliance. Close monitoring by a trained psychiatrist is beneficial for individuals with mood disorders. If patients are in need of more intensive psychiatric treatment at any time during the course of the trial, study personnel will assist in needed evaluation and referral to appropriate treatment settings. Participants will be carefully monitored regarding depressive and other psychiatric symptoms. Patients will be assessed for suicidal ideation at every visit. Participants who, in the opinion of the assessing clinician, have a worsening of suicidal ideation that renders

them at increased risk for study participation will be removed from the study and given an appropriate clinical referral.

Informed Consent

All participants will receive the consent form for the study as well as the Human Subject's Bill of Rights. First, youth patients and parents presenting to their clinical provider's office who express interest in the study will be given a copy of the informed consent form, so they can carefully read the document and discuss the research with their family, friends and/or physician and develop questions to ask the research staff. If they continue to be interested, they will discuss with the study staff the details of the research study using the informed consent document as a guide. This discussion should include all of the required elements of informed consent, e.g., the purpose of the research, the procedures to be followed, the risks and discomforts as well as potential benefits associated with participation, and alternative procedures or treatments, if any, to the study procedures. Participants will always be given the opportunity to ask questions and have them answered by the investigator and, whenever possible, to consult with friends/family and/or their physicians. Once they have read the consent document and their questions are answered, if they agree to participate in the research, they sign and date the informed consent document. The parent/guardian/legally authorized representative will provide consent, and the youth will provide assent. Participants will sign informed consent and only then will any study-related procedures be conducted.

IRB Review

For consistency and efficiency, we will use the UT Southwestern Institutional Review Board (IRB) for all nodes and sites. Before study initiation, the Investigators must have written and dated approval/favorable opinion from the UT Southwestern IRB for the protocol, consent form, patient recruitment materials/process (e.g., advertisements), and any other written information to be provided to patients and documentation from their institution-specific IRB that the UT Southwestern IRB may serve as the centralized IRB for this project.

Data Confidentiality

Potential risks to data confidentiality will be mitigated by requirements for the de-identification of all study data and by security protocols for all data capture systems. All users of the EDC system will be tracked and provided access in a secure fashion following established SOPs for this process. As with all research data, information gathered by the study will be used only for aggregate analysis; it will not be released with any information that identifies research participants. The data managers, statistician, Investigator, and Sponsor do not have access to the identities of patients. That information is retained only at the clinical centers and will be de-identified prior to being uploaded into the repository for data synthesis and analyses. Uses and risks related to data collection will be outlined in the informed consent and reviewed with the participants.

Budget

We anticipate a budget of \$250,000 per Node in the Childhood Depression Network over the entire funding period. Funding will support the Node Lead Investigator and a Study Coordinator, who will be responsible for assisting with identifying potential sites and assisting sites with recruitment and assessment of participants. These funds will also cover participant payments and research study supplies.

References

American Academy of Child and Adolescent Psychiatry (2007). Practice parameter for the assessment and treatment of children and adolescents with depressive disorders. *Journal of the American Academy of Child and Adolescent Psychiatry*, 46:1503-1526.

Asarnow JR, Atkins M, Hoagwood KE, Hughes JL, Kazak AE, Lochman JE, Miranda JM, Piacentini J, Portwood SG, Stancin T, Tynan D, Wysocki T (2015). Psychological science and innovative strategies for informing health care redesign: A policy brief. *Journal of Clinical Child and Adolescent Psychology*, 44(6): 923-932.

Asarnow JR, Rozenman M, Wiblin J, Zeltzer L (2015). Integrated medical-behavioral care compared with usual primary care for child and adolescent behavioral health: A meta-analysis. *JAMA Pediatrics*, 169(10): 929-937.

Curtin SC, Heron M. Death rates due to suicide and homicide among persons aged 10–24: United States, 2000–2017. NCHS Data Brief, no 352. Hyattsville, MD: National Center for Health Statistics. 2019

Emslie GJ, Kennard BD, Mayes TL, Nightingale-Teresi J, Carmody T, Hughes CW, Rush AJ, Tao R, Rintelmann JW (2008). Fluoxetine vs. Placebo to Prevent Relapse of MDD in Children and Adolescents. *American Journal of Psychiatry*, 165(4): 459-67.

Kennard BD, Emslie GJ, Mayes TL, Nakonezny PA, Jones JM, Foxwell AA, King J (2014). Sequential Treatment With Fluoxetine and Relapse-Prevention CBT to Improve Outcomes in Pediatric Depression. *American Journal of Psychiatry*, 171:1083-1090

Kennard BD, Silva SG, Tonev S, Rohde P, Hughes JL, Vitiello B, Kratochvil CJ, Curry JF, Emslie GJ, Reinecke M, March J (2009). Remission and recovery in the Treatment for Adolescents with Depression Study (TADS): Acute and long-term outcomes. *Journal of the American Association of Child & Adolescent Psychiatry*, 48: 187-196.

Mental Health America (2020). State of Mental Health in America. <https://www.mhanational.org/issues/ranking-states>. Accessed February 20, 2020.

Perou R, et al. (2013). Centers for Disease Control and Prevention. [Mental health surveillance among children – United States, 2005—2011](#). *MMWR* 2013;62(Suppl; May 16):1-35.

The Meadows Mental Health Policy Institute for Texas. Estimates of Prevalence of Mental Health Conditions among Children and Adolescents in Texas. March 24, 2016. Available at <https://www.texasstateofmind.org/wp-content/uploads/2016/01/MMHPI-Child-Adolescent-Prevalence-Summary-2016.03.24.pdf>

Texas Department of State Health Services. YRBS Data Brief Texas Youth Risk Behavior Survey Suicidal Behavior. DSHS Data Brief, DSHS 25-15069-9. 2018. Available at <https://texassuicideprevention.org/wp-content/uploads/2019/05/September-Data-Brief-Suicidal-Behavior.pdf>

Twenge JM, Cooper AB, Joiner TE, Duffy ME, Binau SG (2019). Age, period, and cohort trends in mood disorder indicators and suicide-related outcomes in a nationally representative dataset, 2005-2017. *Journal of Abnormal Psychology*, 128(3): 185-199.

U.S. Department of Health and Human Services (2018). Texas Adolescent Mental Health Facts. <https://www.hhs.gov/ash/oah/facts-and-stats/national-and-state-data-sheets/adolescent-mental-health-fact-sheets/texas/index.html>. Accessed February 20, 2020.

U.S. Preventive Services Task Force (2016). Depression in Children and Adolescents: Screening. <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/depression-in-children-and-adolescents-screening1>. Accessed February 20, 2020.

University of Washington (2013). Advancing Integrated Mental Health Solutions. <https://aims.uw.edu/>. Accessed March 15, 2020.

Wissow, L. S., Brown, J. D., Hilt, R. J., & Sarvet, B. D. (2017). Evaluating integrated mental health care programs for children and youth. *Child and Adolescent Psychiatric Clinics*, 26(4), 795-814.