



**Texas Juvenile Justice Department**  
**RESEARCH OR STATISTICAL PROJECT INVOLVING TJJD YOUTH DATA AGREEMENT**  
**CON0001653**

**THIS IS AN AGREEMENT** between the State of Texas, represented by and through the **Texas Juvenile Justice Department**, hereinafter “**TJJD**,” and **University of Texas Medical Branch**, hereinafter “**Research Consultant**.”

Research Consultant has proposed to undertake research related to the work of TJJD. The research project, hereinafter “**Project**,” is described **Attachment 1**, the research proposal, which is incorporated herein. TJJD finds that the proposed research is of benefit to TJJD and will be in furtherance of TJJD’s responsibility under Section 203.007, Human Resources Code, to continuously study the problem of juvenile delinquency in this state. Research Consultant will be considered a professional consultant of TJJD for the purposes of completing the Project and for compliance with Section 58.005, Family Code.

**I.**  
**Purpose**

The purpose of this Agreement is to delineate the terms and conditions of the approved and authorized disclosure of confidential TJJD records under Section 58.005, Family Code, for the purpose of the Project.

Juvenile Justice Information  will  will not be provided to Research Consultant.

If Juvenile Justice Information will be disclosed, the Statement of Data Security must be completed and is incorporated herein by reference.

**II.**  
**Confidentiality**

- 2.1 Research Consultant hereby acknowledges the confidential nature of the information received and agrees to comply with each and every restriction and obligation set forth herein. Research Consultant further acknowledges and agrees that the disclosure of information by TJJD does not constitute a waiver of any applicable provisions or exceptions to disclosure under Chapter 58, Texas Family Code, Chapter 552, Texas Government Code, or any other law or provision.
- 2.2 Research Consultant will comply with all state and federal laws regarding the confidentiality of information received through this Agreement and regarding the confidentiality.
- 2.3 Research Consultant hereby acknowledges that no publication shall contain the name or other identifying information of individual youth who are currently or were previously committed to TJJD, including indicators that could make it possible to identify a youth using other available information.

**III.**  
**Scope of TJJD’s Release**

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- 3.1 TJJD will provide Research Consultant the information and/or data listed in the Project.
- 3.2 Upon execution of this Agreement, TJJD will prepare the information and/or data described above in section 3.1 and electronically deliver to Research Consultant through the TJJD Secure File Transfer (SFT) method within a reasonable amount of time based on the volume of the request.
- 3.3 TJJD will provide assistance and instructions how to receive the information and/or data through the TJJD SFT.

**IV.  
Obligations and General Responsibilities of Research Consultant**

- 4.1 Research Consultant shall:
  - 4.1.1 Use the information and/or data provided only for the purpose described in the Project (**Attachment 1**);
  - 4.1.2 Use the information and/or data in the format provided by TJJD and not in a manner that alters or misconstrues the provided data;
  - 4.1.3 Prior to dissemination of any information concerning the Project, immediately notify TJJD of any material changes in the purposes or objectives of the Project or in the manner in which the information and/or data will be used; unless TJJD approves the changes, any information regarding the Project may not be disclosed;
  - 4.1.4 Limit access to the information and/or data to only employees, faculty members, students, or subcontractors of the Research Consultant who are working on the Project and whose responsibilities cannot be accomplished without such access;
  - 4.1.5 Prohibit the disclosure, in any form, of data that identifies an individual, including combinations of data that could be used to identify an individual;
  - 4.1.6 Prohibit the disclosure, distribution, review, copying, or duplication of or access to information and/or data provided for any purpose other than the Project purpose;
  - 4.1.7 Secure a written agreement that contains a provision that restricts access, removal, and portability of all Project information and/or data by any employee, faculty member, student, or subcontractor, working on the Project after that person's affiliation, association, or employment with Research Consultant has ended;
  - 4.1.8 Provide a draft copy of the Project report, article, or publication to TJJD prior to dissemination;
  - 4.1.9 Notify TJJD immediately upon discovery of any unauthorized use, disclosure, or any other breach of this Agreement and cooperate with TJJD to regain possession and/or prevent its further unauthorized use or disclosure; and
  - 4.1.10 Destroy all information and/or data no matter the format, including all originals, copies, extracts, or other forms and/or formats, no later than 30 days of when the Project has been completed and notify TJJD of such destruction no later than 7 days after the destruction is complete. Research Consultant must request and receive permission in writing from TJJD to preserve data for a period of time beyond 30 days from completion of the project as described in the Project Timeline (Attachment A). In the event an approved publication (per 4.1.8) is accepted to a journal requiring a longer period of

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data retention, TJJD agrees in principle to provide permission for data preservation during the required period as long as this Agreement is in place.

4.2 Research Consultant shall not:

- 4.2.1 Disclose in any Project report, or in any other manner whatsoever, any information or data in a form that is identifiable to an individual, including combinations of data that could be used to identify an individual; or
- 4.2.2 Make copies of any of the information and/or data provided other than what is necessary for the Project.

**V.  
TJJD's Right to Monitor Research Consultant Activities**

Research Consultant agrees that TJJD shall have the right, at any time, to monitor, audit, and/or review the activities and policies of Research Consultant in order to assure compliance with this Agreement. Further, TJJD has the right to review Research Consultant's work on the Project, including, but not limited to, Project findings and reports, prior to dissemination or publication.

**VI.  
Term and Termination**

- 6.1 **Term.** The term of this Agreement shall commence upon the date of full execution of this Agreement and shall continue through the earlier of either completion of the Project or for a period of three years. At the end of such three-year term, this Agreement may be renewed upon mutual written agreement of the parties. The confidentiality provisions contained herein shall survive upon termination of the Agreement.
- 6.2 **Termination.**
  - 6.2.1 TJJD reserves the right to terminate, for convenience, its obligations under this Agreement by giving thirty (30) days' written notification to Research Consultant.
  - 6.2.2 In the event Research Consultant fails to comply with any term of this Agreement, TJJD shall have the right to take such actions as it deems appropriate, including termination of this Agreement and/or a prohibition of granting permission to Research Consultant to perform similar research projects in the future.
  - 6.2.3 If TJJD terminates this Agreement, Research Consultant (or any person or entity granted access to the information and/or data), no later than 10 days from the date of termination, shall destroy all information and data, no matter the format, including all originals, copies, extracts, or other forms or formats, and notify TJJD that the destruction is complete. The confidentiality provisions contained herein shall survive upon termination of the Agreement.

**VII.  
TJJD's Property Rights**

Any patentable product, process, or idea that results from the performance of this Agreement AND for which TJJD has expended appropriated funds becomes the property of TJJD. Additionally, as consideration for TJJD providing Research Consultant the information and/or data under this Agreement, Research Consultant agrees to

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provide TJJD with a no-cost, royalty-free license on any patentable product, process, or idea that results from the performance of this Agreement.

**VIII.  
Hold Harmless**

- 8.1 To the extent permitted by the Constitution and the laws of the state of Texas, Research Consultant shall indemnify, defend, protect, and hold harmless TJJD or any of its employees from any claims, damages, or other liability arising as a result of disclosure by Research Consultant of any information received pursuant to this Agreement or for any acts by Research Consultant that are libelous or slanderous or that violate a right of confidentiality.
- 8.2 TJJD makes no representations or warranties, express or implied, as to the accuracy and completeness of the information disclosed. Research Consultant acknowledges and agrees that TJJD shall not be responsible for Research Consultant's reliance on the information and/or data provided.

**IX.  
Governing Law, Venue, and Sanctions**

- 9.1 This Agreement is being executed, delivered, and performed in the state of Texas. The laws of the state of Texas shall govern the validity, construction, enforcement, and interpretation of this Agreement. In any legal action arising from this Agreement, the laws of the state of Texas shall apply and venue shall be in Travis County, Texas.
- 9.2 Research Consultant acknowledges and agrees that failure to comply with the terms of this Agreement, including any misuse or wrongful disclosure, may result in administrative or legal action and may subject Research Consultant to civil or criminal penalties imposed by state or federal law.

**X.  
General**

This document constitutes the complete and final agreement between TJJD and Research Consultant. Any other oral or written agreements between the parties concerning the subject matter of this Agreement are of no force or effect after the effective date of this Agreement. In the event that any provision or part of this Agreement is found to be invalid or unenforceable, only that particular provision or part, and not the entire Agreement, will be inoperative. Research Consultant and TJJD agree that any modifications or amendments to this Agreement must be in writing and signed by all parties. Neither this Agreement nor any duties or obligations herein shall be assignable by Research Consultant without express, prior, and written approval from TJJD.

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*The parties hereto in their capacities as stated affix their signatures and bind themselves to the terms of this Agreement.*

THE STATE OF TEXAS, acting by and through the Texas Juvenile Justice Department:

[Redacted Signature]

Date: 10/14/2024

Shandra Carter  
Executive Director, Texas Juvenile Justice Department

Research Consultant:

UTMB Investigator:

[Redacted Signature]

Date: 10/7/24

Rocksheng Zong, MD, MHS  
Associate Professor, Dept of Psychiatry & Behavioral Sciences

UTMB Authorized Signing Official:

[Redacted Signature]

Digitally signed by Nancy Devino,  
PhD, CRA  
Date: 2024.10.11 11:00:01 -05'00'

Date: \_\_\_\_\_

Nancy Devino, PhD, CRA  
Director, Sponsored Programs



# Research Project Proposal

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## Project Title

**Youth Mental Health in Juvenile Justice**

## Principal Researcher

Name	Position, Title, or Other Qualification/Credential	University or Organization
<b>Rocksheng Zhong, MD, MHS</b>	<b>Associate Professor</b>	<b>UTMB Dept of Psychiatry &amp; Behavioral Sciences</b>

## Project Supervisor

N/A (principal researcher is the project supervisor)

Name	Position, Title, or Other Qualification/Credential	University or Organization

## Other Researchers

*For all other researchers participating in the project, list the name; position, title, or other qualification/credential; and university or organization.*

Danielle Busby, PhD, Assistant Professor, UTMB Dept of Psychiatry & Behavioral Sciences  
Denise Baughn, MD, Assistant Professor, UTMB Dept of Psychiatry & Behavioral Sciences  
Navin Oorjitham, MD, Assistant Professor, UTMB Dept of Psychiatry & Behavioral Sciences  
Jacques Baillargeon, PhD, Professor and Chair, UTMB Dept of Epidemiology  
Biai Digbeu, MPH, Biostatistician, UTMB Dept of Biostatistics  
Yong-Fang Kuo, PhD, Professor and Chair, UTMB Dept of Biostatistics

## Purpose of Project

Thesis     Dissertation     Professional Paper     Other (specify):

## Executive Summary

*Provide an overview of the proposed project.*

The mental health of juvenile justice-involved youth is of paramount importance to public health and safety. The United States incarcerates more children per capita than any other developed country. Not only is juvenile justice involvement associated with a multitude of negative mental health outcomes, notably trauma and suicide, but unmet mental health needs in juvenile justice also have deleterious effects on long-term socioeconomic variables, such as education, employment, and adult criminal justice involvement.

The juvenile justice population has changed substantially in the last two decades, owing to demographic shifts and COVID-19. Yet, scant research has investigated the characteristics of justice-involved youth with mental illness and the effects of juvenile justice mental health in the wake of these changes. UTMB, through Correctional Managed Care (CMC), partners with the Texas Juvenile Justice Department (TJJD) to provide medical and mental health services for justice-involved youth in the state of Texas.

This project aims to use TJJD electronic medical record, psychological services, and administrative data from 2014 to 2024 to describe the epidemiology of the juvenile justice population over time and develop predictive models for mental health outcomes and healthcare utilization, suicide and violence risk, and juvenile offenders' correctional needs. We pay special attention to the impacts of trauma and adverse childhood experiences in this group, given their widespread prevalence and known effects on mental health and suicide risk.

## Research Questions

*Identify the questions to be examined that are related to the requested juvenile justice information and/or data.*



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## Research Questions

We propose to study three specific aims:

**Specific Aim 1:** We will characterize the epidemiology of mental health in the juvenile justice system organized in serial year cohorts, identifying the changes in demographics, prevalence rates of mental disorders, and healthcare utilization (most notably, psychotropic medication prescribing patterns).

**Hypothesis 1:** The prevalence of mental disorders and per capita healthcare utilization increased from 2014 to 2024, with rates climbing especially quickly during the COVID-19 pandemic.

**Specific Aim 2:** We will develop multivariable predictive models for development of mental illness and effectiveness of mental health treatments, accounting for such variables as juvenile detainees' sociodemographic factors, education, trauma and adverse experiences, offense information, medical and psychiatric diagnoses, clinical encounters, medication prescriptions, and involvement in specialized treatment programs.

**Hypothesis 2:** Disadvantaged and minority backgrounds, lower educational attainment, higher degrees of trauma and adverse experiences, and offense severity will be associated with mental illness, greater mental healthcare utilization, and lower rates of successful program completion.

**Specific Aim 3:** We will develop predictive models that assess risk factors for suicide and violence and their consequent correctional interventions. Important variables to assess will include juvenile detainees' suicide risk level, suicidal ideations, and suicidal behaviors, as well as violent behaviors and infractions that can result in greater correctional supervision and time incarcerated.

**Hypothesis 3:** Lower educational attainment, higher degrees of trauma and adverse experiences, offense severity, mental illness, and mental healthcare utilization will be associated with higher rates of suicidality, violent behavior, and need for additional correctional intervention.

## Research Design

*Provide a description of the research design related to the requested juvenile justice information and/or data.*

This study is a deidentified population-based retrospective review of data found in UTMB CMC's electronic medical record (EMR), TJJD psychological services records, and TJJD administrative records. To maintain privacy of subjects, all CMC and TJJD data will be maintained in a double password secured system. Additionally, all data will be stripped of personal identifiers before it is analyzed. All analyzed data will be presented in aggregate form such that no subject may be identified.

At any given time, approximately 700 to 1,000 children are in TJJD custody. All juveniles detained in TJJD are required to have medical and mental health examinations at the time of intake; the evaluation lasts approximately 60 minutes and consists of a detailed history, comprehensive physical exam, and any appropriate laboratory testing. All diagnoses are made by board-certified child and adolescent psychiatrists or advanced practice providers at the time of each patient's initial evaluation and/or subsequent medical encounters and are classified according to the International Classification of Disease (ICD-10) coding system. TJJD Psychological Services providers also assess mental health needs and assign specialized service programming, make level of care and placement determinations, and refer for additional psychiatric evaluation as necessary.

Information about detainees' diagnoses, clinical status, healthcare utilization, medication prescriptions, socioeconomic variables, and demographics are recorded in the EMR. In addition, TJJD Psychological Services maintains several internal databases containing information about juveniles' Adverse Childhood Experiences (ACEs), suicidality, suicide risk assessments, level of monitoring, treatment needs assessments, and placement in and completion of specialized programs (e.g., addiction, sexual offender, capital and violent offender). Furthermore, TJJD conducts Residential Positive Achievement Tool (R-PACT) assessments of all youths every 90 days. The R-PACT is a validated risk and needs assessment tool developed by the Florida Department of Juvenile Justice to identify criminogenic risk and protective factors, guide service provision, and track progress over time. It contains factors concerned with suicide and violence risk and has been shown to be associated with rates of recidivism.



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## Research Design

We will develop a merged deidentified database containing these data for all juveniles detained in TJJD for any duration from 2014 through 2024. We will apply standard epidemiological and public health descriptive statistical analyses to ascertain rates of mental disorders and healthcare utilization (Aim 1). We will develop regression models that will identify predictors and risk factors for mental illness (Aim 2) and suicide and violence risk (Aim 3) in the TJJD population.

## Research Methodology

*Provide a description of the research methodology (including applicable statistical methods or models) related to the requested juvenile justice information and/or data.*

With assistance from data analysts at TJJD and UTMB CMC, we will create merged databases of all juveniles detained in TJJD for any duration from 1/1/14 through 12/31/24. We will cross-reference and link data entries according to TJJD identification number and date of birth, both of which are universally maintained in the UTMB CMC and TJJD electronic medical record, psychological services records, and administrative records. Once these merged databases are created, all identifying information will be removed, and each unique subject will be assigned a randomly generated dummy identification number. The variables under study are listed in the next section.

Following data acquisition and merge, the combined dataset will be transmitted via secure file transfer to the UTMB School of Public and Population Health (SPPH) Department of Biostatistics and Data Science, where biostatisticians working with the research team will then be responsible for data management, security, and analysis. At no point will the research team have access to identifiable chart information.

## Requested Information and/or Data

*Itemize a comprehensive list of the requested juvenile justice information and/or data.*

- ICD-10 (or ICD-9 codes if ICD-10 codes were not yet implemented that year) diagnostic codes
- Sociodemographic variables:
  - o Age
  - o Gender (self-identified by detainee)
  - o Race
  - o Ethnicity
- Education:
  - o Tests of Adult Basic Education (TABE) scores measuring reading and mathematics levels
  - o Texas Education Agency (TEA) special education designation
- Detention status:
  - o Date of detention
  - o Date of release from detention
  - o Type of offense
- Healthcare utilization:
  - o Medication prescriptions (Dates of prescription, National Drug Code, and drug name)
  - o Percent of missed and refused medications
  - o Number of mental health outpatient level of care encounters



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## Requested Information and/or Data

- o Number of medical outpatient level of care encounters
- o Percent of missed and refused outpatient level of care encounters
- o Number of infirmary level of care encounters
- o Number of emergency department level of care encounters
- o Number of psychiatric crisis management encounters
- o Number of psychiatric hospitalizations
- o Number of medical hospitalizations
- o Admission to specialized treatment programs (sexual offenders, addiction, behavioral stabilization, crisis stabilization, youthful offenders, capital/serious violent offenders)
- o Completion of specialized treatment programs
- Needs assessments:
  - o Treatment hierarchy assessment (numerical score based on a Risk-Need-Responsivity model)
  - o Residential Positive Achievement Tool (R-PACT, a juvenile justice risk and needs assessment tool that includes domains related to education, employment, interpersonal relationships, substance use, mental health, coping skills, impulsivity, and aggression)
- Suicidality:
  - o Suicidal ideation (dates of onset)
  - o Suicidal behavior, including self-injury and suicide attempts (dates of onset)
  - o Days on suicide watch
  - o Completed suicides
  - o Suicide attempt history
  - o Staff assessment of suicide risk and disposition (not on suicide alert, suicide alert in general population, or suicide alert in protective custody) and level of monitoring (close, constant, or 1:1 observation)
- Violent behavior:
  - o Rule violations (date and type of violation)
  - o Assaults on staff (date and frequency)
  - o Assaults on peers (date and frequency)
- Adverse Childhood Experiences (ACEs):
  - o ACEs consist of ten original items, which have since been expanded: emotional abuse, physical abuse, sexual abuse, emotional neglect, physical neglect, domestic violence, household substance abuse, mental illness in the household, parental separation or divorce, and incarceration of a household member. Prior research has associated ACEs with a variety of negative long-term health outcomes, including chronic disease and mental illness.

*Provide a description of how the requested juvenile justice information and/or data relate to the research questions.*

The requested data pertain to juvenile detainees' sociodemographic information, juvenile justice-related parameters, physical and mental health, suicidal and violent behavior, and treatment needs. Accounting for these factors will allow us to develop sophisticated epidemiological and predictive models about youths' mental health outcomes and suicide and violence risk.

## Statement 1

*Provide a statement describing why juvenile justice information and/or data are needed for the proposed project.*



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## Statement 1

This study examines the epidemiology and public health of juvenile justice-involved individuals. Without access to the health information of juvenile detainees, this research would not be possible, and important information about the public health of juvenile justice-involved youths would not be available for clinicians and policymakers.

## Statement 2

*Provide a statement describing how the proposed project will benefit TJJD and/or the juvenile justice system.*

This project will advance our understanding of the public health and epidemiology of psychiatric disorders, mental health treatment, and suicide and violence risk in the juvenile justice setting. We expect to ascertain rates of various illnesses in the juvenile justice setting and assess risk factors and predictors of those illnesses. This information is likely to benefit future juvenile detainees, TJJD, and society at large by helping to clarify public health needs in an underserved population, identify targets for disease prevention and intervention, and determine appropriate resource allocation.

## TJJD Staff Time

*Identify the amount of TJJD staff time needed to complete the proposed project, provide technical assistance, and/or compile data.*

We estimate that the project will require approximately 20 hours of TJJD staff time to assist with compilation, deidentification, and secure transmission of data.

## Research Participants

*Would the proposed project include the involvement of research participants (i.e., youth in TJJD custody and/or TJJD staff)?*

Yes (Complete the three questions below before continuing with the Project Timeline section.)

No (Skip the three questions below and continue with the Project Timeline section.)

*Identify the number of research participants.*

*Identify the amount of time required by each research participant.*

*Describe the provisions that will be in place to protect the confidentiality of research participants.*

## Project Timeline

*Provide a timeline for the proposed project (i.e., dates for collecting juvenile justice information and/or data, conducting analysis, writing report).*

Aug 2024 – Nov 2024: TJJD review and approval

Dec 2024 – Mar 2025: Data requests and acquisition

Mar 2025 – June 2024: Data merge, cleaning, deidentification, and management

July 2025 – Dec 2025: Data analysis: descriptive statistics and development of predictive models

Jan 2026 – Aug 2026: Preparation of findings for publication/presentation

## Funding Source and Amount

Source: Texas Child Mental Health Care Consortium New and Emerging Children's Mental Health Researchers Initiative  
Amount: \$499,999.30

If this is not applicable, briefly explain the reason.



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### Included Attachments

Yes N/A

- |                                     |                                     |   |
|-------------------------------------|-------------------------------------|---|
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | Institutional Review Board (IRB) approval                             |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | Study instruments, surveys, etc.                                      |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | Study consent forms   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | Completed Research and Analytical Testing System (RATS) questionnaire |



## Research and Analytical Testing System Questionnaire

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The Research and Analytical Testing System (RATS) is designed to gather information on research projects being conducted on or with children under the jurisdiction of juvenile probation departments or the Texas Juvenile Justice Department (TJJD). The reporting of this information is required under Section 203.007, Human Resources Code.

1. Principal Researcher Name: Rocksheng Zhong, MD, MHS Title: Associate Professor
2. Research Project Name: Youth Mental Health in Juvenile Justice
3. Sponsoring Entity: UTMB
4. Type of Project (select primary type):
  - Medical
  - Pharmaceutical
  - Psychological
  - Social
  - Other If other, please specify: \_\_\_\_\_
5. Number of Juvenile Participants Involved in the Project: ~6000 records (records for all persons detained in TJJD for any duration from 1/1/14 through 12/31/24 and had at least one clinical encounter with a member of the medical, mental health, or psychological services staff that generated an entry in the electronic medical record, psychological services records, or administrative records)  N/A (project involves secondary data only)
6. Location of the Juvenile Participants Involved (select all that apply):
  - Detention
  - Non-secure Placement
  - Secure Placement
  - Juvenile Justice Alternative Education Program (JJAEP)
  - Probation Department Office
  - TJJD
  - Other If other, please specify: \_\_\_\_\_
  - N/A (project involves secondary data only)
7. Type of Contact (select all that apply):
  - Direct Contact with Juveniles by Researcher
  - Direct Contact with Juveniles by Officers/Staff
  - Collection of Juvenile Data Records
8. Institutional Review Board (IRB) Number: 24-0227
9. IRB Approving Entity: UTMB
10. Project Begin Date: 9/1/2024
11. Data Collection Begin Date: 9/1/2024
12. Data Collection End Date: 3/31/2025
13. Project Completion Date: 8/31/2026
14. Status: Pending

06-Aug-2024

**MEMORANDUM**

TO: Rocksheng Zhong  
Psychiatry/Behavioral Science 143700

FROM:   
Alexander Duarte, MD  
Vice-Chairman, IRB #2

RE: Initial Study Approval

IRB #: IRB # 24-0227

Submission Number: 24-0227.003

TITLE: Youth Mental Health in Juvenile Justice

DOCUMENTS: Request for Review of Expedited Research  
Data collection sheet  
Protocol  
Signature page Modify  
TJJD letter of support

The UTMB Institutional Review Board (IRB) reviewed the above-referenced research protocol via an expedited review procedure on **06-Aug-2024** in accordance with 45 CFR 46.110(a)-(b)(1). Having met all applicable requirements, the research protocol is approved. The approval for this research protocol begins on **06-Aug-2024**.

Continuing Review for this protocol is not required, as outlined in 45 CFR 46.109. A Status Report is required to be submitted to the IRB every three (3) years. A reminder will be sent approximately 90 days prior to its due date. *Please be advised failure to submit a Status Report may result in the study being administratively closed. If the study is administratively closed, the project will require resubmission as a new proposal to continue.*

**The next Study Status Report will be due on 06-Aug-2027.**

The Principal Investigator is still responsible for:

1. Submitting amendments for protocol changes.
2. Reporting Adverse Events, Protocol Violations, and Unanticipated Problems, as outlined in IRB policies and procedures.
3. Closing the project once it ends, or when personal identifiers are removed from the data/biospecimens and all codes and keys are destroyed.
4. Compliance with UTMB Health Information Management [Research Tracking and Accounting of Disclosure of PHI](#) policy.

**The requirement to obtain informed consent is waived in accordance with 45 CFR 46.116(d).**

The approved number of subjects/medical records/specimens to be enrolled/utilized is **6000**. If, the approved number needs to be increased, you first must obtain permission from the IRB to increase the approved sample size.

If you have any questions, please do not hesitate to contact the IRB office via email at [IRB@utmb.edu](mailto:IRB@utmb.edu).