The University of Texas at Austin
Institutional Review Board
Research Proposal

STUDY INFORMATION

For studies following a multi-center or sponsor protocol, please use this guidance to assist in your completion of this form.

For questions regarding definitions, policies, or terms referenced below see the policies and procedures manual.

Study Title and Number from IRBaccess
Migration & Health: Latinos in Austin, Texas
2018-12-0069

Principal Investigator			
Name	Position	UT EID	E-mail Address
Pinedo	Assistant Professor	Mp45237	mpinedo@austin.utexas.edu
If principal investigator is a student, describe how the PI is qualified/trained to conduct this study.			
Click or tap here to enter text.			

Faculty Sponsor *(required if the PI is a student)*			
Name	Position	UT EID	E-mail Address
First Last	Title	XXX##	jdoe@utexas.edu
Describe how faculty sponsor will oversee the conduct of the study.			
Click or tap here to enter text.			

Primary Point of Contact (if different from PI)			
Name	Position	UT EID	E-mail Address
First Last	Title	XXX##	jdoe@utexas.edu

Additional Research Staff	
☒	Research staff other than the principal investigator will conduct human subject research.

If additional personnel will be engaged in conducting research human subject research, complete and upload the Research Personnel Form

Engaged in human subject research is defined as contact or interaction with research participants through recruitment, informed consent process, data collection, analysis of or access to identifiable research data.

Purpose and Rationale for Conducting Research

Hypothesis

This is an exploratory qualitative study, hence, there are no hypotheses. This study will explore the role that migration-related stressors have on the mental health and substance using behaviors of US-citizen and migrant Latinos living in Austin, Texas.

Study Background

Given the current political climate, migration-related issues in the US have received wide media and public attention. Migration-related stressors (e.g., anti-immigration sentiments and policies, deportations, immigration raids) create hostile environments for Latino migrants. Latino migrants experience heightened stress due to perceptions of constant surveillance and scrutiny, which impacts their well-being. Migration-related stressors also affect US-citizen Latinos. For example, US-citizen Latinos living in states with more punitive policies against migrants or who have had a family member deported are at greater risk for poorer mental health outcomes. It is imperative to better understand the role of migration-related stressors on community health. The emotional impacts associated with migration-related stressors may perpetuate or exacerbate existing health disparities related to mental health and substance abuse among Latinos. Austin has a significant Latino and migrant community. Approximately 35% and 18% of Austin residents are Latinos and migrants, respectively. Anti-immigration sentiments, including increased immigration raids and deportations, have been a rising concern in the city. However, the impacts of migration-related stressors on the health of Austin community members has not been empirically assessed making this line of research timely and significant. The proposed study will use qualitative methods to characterize the mental health and substance using behaviors of US-citizen and migrant Latinos in Austin within the context of migration-related stressors.

Design and Methodology

This study will recruit a community sample of 40 Latinos (20 US-citizens, 20 migrants; half by gender). Participants will be recruited via Craigslist advertisements, flyers in community agencies, and flyer distribution at community events. Interested participants will be screened for study eligibility. We will purposefully sample participants; those who agree to participate in the study will undergo an in-depth qualitative interview conducted by a bilingual and bicultural research assistant (RA). Interviews will be audio-recorded and transcribed. Participants will be asked for consent to be audio-recorded. If a participant wishes to not be audio-recorded, interviewer will take hand written notes.

Data Analysis

The qualitative interview will be transcribed verbatim, and uploaded into the NVivo software (QSR International Pty Ltd. Version 11). A coding scheme will be created based on the major themes in participants' narratives using an inductive, iterative approach to identify emergent themes. Once the coding scheme is finalized, two independent coders will code each transcript.

Coders will meet regularly to compare coded transcripts and discuss discrepancies. Discrepancies will be resolved through discussion and consensus. Once the coding was complete, frequencies of coded themes will be examined overall, and by nativity to elucidate differences and similarities.

Funding and Regulatory Oversight					
Check all agencies that fund or hold regulatory oversight over the research activities. *If study activities are regulated by the FDA, check FDA here. The FDA regulates any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit..*					
☐	Food and Drug Administration (FDA) Regulated				
☐	NIH	☐	Department of Defense (DoD) *Complete Supplemental IRB Application - DoD*	☐	Dept. of Education (DoEd)
☐	Dept. of Energy (DOE)	☐	Department of Justice DOJ/NIJ	☐	Environmental Protection Agency (EPA)
☐	Bureau of Prisons				
☐	Other Federal Agencies: Click here to enter text.				
☐	Industry/Private Sponsor: Click or tap here to enter text.				
☐	Other External Funding: Click or tap here to enter text.				
OSP: ###					

PROCEDURES

Study Elements					
Check any that apply to your study. This is not meant as a comprehensive record of your entire study. *A full description of all study procedures should be provided in the procedures section below or the applicable supplement form.*					
☐	Bio-specimen *Complete Supplemental IRB Application – Biospecimens*	☐	Biometrics	☐	Registry or repository *Complete Supplemental IRB Application - Repository*
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International research	☒	Interview/ Survey	☐	MRI

	Complete Supplemental IRB Application - International				
☐	PHI *Complete Supplemental IRB Application - PHI*	☐	Observation	☐	Record Review (Prospective)
☐	Record Review (Retrospective)	☐	Screening Procedures	☐	Sensors (Externally Placed)
☐	Sensors (Inserted)	☒	Video/Audio Recording	☐	X-Ray
Interventions					
☐	Drug/Biologic *Complete Supplemental IRB Application - Drugs*	☐	Device *Complete Supplemental IRB Application - Device*	☐	Behavioral
Additional Oversight					
☐	Biohazards, Recombinant DNA, or Gene Transfer *Upload IBC approval letter*	☐	Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos	☐	Radiation exposure without direct clinical benefit *Upload radiation safety approval*
Additional Questions:					
☐	This study involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.				

Procedures
Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable: *a) All study procedures, in sequential order* *b) All research measures/tests that will be used (state if questions or measures are standardized or published)* *c) Secondary data or specimens that will be obtained, how they will be collected, and how they will be used* *d) Where each activity will take place, the duration of each, and who will perform each activity* *e) Include time commitment of participants* *f) Mark all optional procedures as [OPTIONAL]*
This study will recruit 40 Latinos residing in Austin for qualitative interviews. Inclusion criteria for this study include: (1) ≥ 18 year of age, (2) Latino racial/ethnic background, (3) speaks English or Spanish, (4) resident of Austin, (5) reports at least one migration-related stressor, and (6) reports poor mental health status, hazardous alcohol use, or substance use (past year). In recruiting our participants, we will implement a quota to recruit 20 US-citizen Latinos and 20 migrants (10 per gender). Participants will be recruited through diverse methods (see Recruitment).

Procedures

Human subject involvement for this study involves the screening of potentially interested participants for eligibility via a short structured questionnaire (~7 minutes) and conducting an in-depth, open-ended, qualitative interview (~45 minutes). A trained bilingual Graduate Research Assistant (GRA) will screen participants in person or by phone. Interested potential participants will also have the option of completing the screener questionnaire online (self-administered).

The screening survey will include basic demographic characteristics such as age, gender, country of origin, place of residence, employment status, and educational attainment. To characterize participants as US citizens or migrants, we will ask: "Were you born in the US?" Nativity does not imply immigration status (e.g., legal permanent resident, naturalized US-citizen) and is a common question in national surveys (e.g., US Census). The screener question will also collect data on migration-related stressors and health to aid in the interpretation of findings. Migration-related stressors will include: "Would you say that attitudes and sentiments towards migrants in Austin are unfavorable or hostile?" "Have you ever witnessed or experienced an immigration raid?" "Do you personally know someone that had been detained during an immigration raid?" and "Do you personally know someone that had been detained or deported?" Health-related questions will include self-reported health status, mental health status via the Patient Health Questionnaire (PHQ-4; questions), alcohol use behaviors via the Alcohol Use Disorder Identification Test (AUDIT-C; 3 questions), and drug use history via the Substance Use Brief Screen (SUBS; 2 questions). Other general questions (e.g., general health), not directly related to our eligibility criteria, will be included to reduce discomfort that may arise from only asking sensitive information (e.g., alcohol and drug use) and to keep potential participants from guessing the eligibility criteria. At the end of the screener questionnaire, participants who meet the study's eligibility criteria will be asked to provide their first name, email, and telephone number, if they are interested in participating in the qualitative interview and consent to being contacted if selected for the study. We will purposefully sample participants from this pool of eligible participants.

Qualitative interviews will be ~45 minutes in length and be audio-recorded. All participants will receive a modest $40 cash incentive as compensation for their time after completing the interview. Interviews will be conducted by a bilingual and bicultural GRA. Dr. Pinedo has developed a semi-structured interview guide consisting of pre-determined open-ended questions and specific probes (included in this application). This guide was developed using migration as a social determinant of health framework. This framework posits that health outcomes and behaviors are products of larger structural forces that are directly associated with the migrant experience (e.g., anti-immigration policies, living and working conditions, impacts of deportation). Questions will focus on the migrant experience in Austin, perceptions and impact of immigration enforcement and deportations in Austin community, and how migration-related stressors influence mental health and substance using behaviors.

Procedures

Alternatives to Participation in this Study
The alternative to participating in this study is to not participate in the study.

LOCATIONS

Study Locations					
Identify the sites where study activities will occur under the direction of UT Investigators.					
☒	UT Austin	☐	UT Health Austin	☐	Dell Seton Medical Center *Upload S.A.T. submission receipt*
☐	Dell Children's Medical Center *Upload S.A.T. submission receipt*	☐	K-12 schools/district	☐	Day care center
☐	Seton Medical Center Austin *Upload S.A.T. submission receipt*	☐	CommunityCare		

External Locations	
Include any non-UT site where UT or non-UT personnel will conduct consent, data collection, intervention, or analysis of identifiable data under the direction of the UT principal investigator. *If UT Austin will serve as the reviewing IRB for a multi-site study (study involves collaboration with sites or individuals external to UT Austin who are engaged in human subjects research), contact RSC to verify the UT IRB will serve as the reviewing IRB.* *Once verified, each relying site must complete the IRB Reliance Form.* *Additional rows may be generated by clicking the + button to the right of the row while its contents are selected. Click in the table below to access the Repeating Section Content Control.*	
Site Name	IRB Oversight Plan
Private community settings (e.g., Austin library)	N/A

Participant's home (in a private setting)	N/A
Additional Questions	
Will UT act as a central coordinating site?	N/A
Describe procedures to communicate SAEs, UPs, and modifications to external sites.	Click or tap here to enter text.

SUBJECT POPULATION

Protected Subject Populations

Select all populations specifically studied under this research.

☐	Active military personnel	☐	Children	☐	Decisionally impaired adults
☐	Emancipated minors	☐	Fetuses	☒	Individuals with limited English proficiency
☐	Neonates	☐	Pregnant women	☐	Prisoners *Complete Supplemental IRB Application - Repository*
☐	UT Students				

Research Participant Information

Describe the research population. If describing multiple populations, provide group names to assist with review and feedback.

Additional tables may be generated by clicking the + button to the bottom right of the subsection while its contents are selected. Click in the table below to access the Repeating Section Content Control.

Participant Group:	**Latinos residing in Austin, Texas**			
Age range	18 To 100	☒	Translated consent/assent:	Spanish
Gender	Any			
Inclusion criteria	(1) ≥ 18 year of age, (2) Latino racial/ethnic background, (3) speaks English or Spanish, (4) resident of Austin, (5) reports at least one migration-related stressor, and (6) reports poor mental health status, hazardous alcohol use, or substance use (past year).			
Exclusion criteria	(1) ≤ 18 years of age, (2) not of Latino racial/ethnic background, (3) does not speak English or Spanish, (4) not a resident of Austin, (5) does not report any migration-related stressors, and (6) does not			

	report poor mental health, hazardous alcohol use, or substance use (past year)
Population info	Latinos residing in Austin, Texas

Total Sample Size	
Total number of participants for all participant groups	N = 40 (20 US-citizen Latinos, 20 migrant Latinos)
Sample size rationale	Sample size of 20 is large enough to reach saturation of data per group. A total sample of 40 will allow sufficient power to do comparative analyses.

SCREENING & RECRUITMENT

Identification and Screening	
☐	This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either: 1. Oral or written communication with the prospective subject or LAR 2. By accessing records containing identifiable private information or stored identifiable biospecimens
	Describe the identification and/or screening procedures:
	Potential subjects will be screened for eligibility by responding to a self-administered (via online) or interviewer-administered questionnaire (via telephone or in-person). The potential participant will have the option of being screened through whatever means he or she is most comfortable with. Participants will provide informed consent orally or online for the screening process, which determines eligibility for the study only. All participants of the study will be informed that (1) participation in the screener questionnaire is voluntary, (2) they have the right to refuse to answer any question(s), (3) they have the right to terminate the interview at any time without penalty, (4) all information disclosed will be confidential and anonymous, and (5) questions will cover topics relating to socio-demographics, migration, health, and alcohol and drug use.

Recruitment
Select all recruitment methods utilized for this research and describe the recruitment process.

Upload copies of recruitment materials/scripts to IRBaccess.

☒	E-Mail	☒	Flyer	☒	In-Person
☐	Letter	☐	Social Media	☐	Research Pool
☐	Telephone/Text	☐	Snowball sampling	☒	Web-posting
☐	Word of Mouth	☐	Other: Click or tap here to enter text.		

Describe the recruitment process including where recruitment will take place.

Participants will be recruited through diverse means. First, we will place advertisements on Austin's Craigslist site. Craigslist has been documented to be an effective strategy to recruit participants from hard-to reach populations. Importantly, PI Dr. Pinedo has successfully used Craigslist to recruit Latino participants for qualitative interviews. Craigslist ads will include basic information regarding the purpose of the study. Briefly, these ads will state that we are conducting a study to learn more about Latino's: (1) opinions about migration-related issues in Austin; (2) their health, including mental health, alcohol use, and drug use; and (3) their health needs. Text that explicitly states that this study will not collect information on immigration status will be included. These ads will also include a link to our study website, where potential participants can learn more about the study, verify its legitimacy, and access a short online screening survey. This website will be integrated into a tab on Dr. Pinedo's existing Migration and Health Lab website (https://sites.edb.utexas.edu/mhl/). These ads will also include the project's direct telephone number that participants can contact for more information or if they would like to be screened for eligibility over the phone; the RA will screen these participants over the phone. Second, we will contact and coordinate with community agencies (e.g., Migrant Clinicians Network, Casa Marianella, Mexican Consulate) that cater to Latino and migrant communities in Austin. We will distribute flyers, (containing the same information as the Craigslist ads) to these agencies to promote our study. Third, we will distribute flyers advertising our study at local community events. Finally, GRAs will be present at these local agencies and community events, granted with permission from the agencies and community partners, to screen and recruit potential participants. At the end of the screener questionnaire, only eligible participants will be asked to provide their first name, email, and telephone number, if they are interested in participating in the in-depth telephone interview. We will purposefully select participants from those who meet our eligibility criteria.

OBTAINING INFORMED CONSENT

Consent Overview

Select all applicable.

See IRB Policies and Procedures Section 6 for a description of informed consent.

See IRB Policies and Procedures Section 12.4 for a description of assent/parent permission.

	Obtaining Written Consent		Requesting Waiver of Documentation of Informed Consent
☒	*Complete the Consent and Assent Processes section below*	☐	*Complete the Consent and Assent Processes and the Waiver of Documentation of Consent sections below*
	Requesting Waiver of Informed Consent		Requesting Alteration of the Required Elements of Informed Consent
☐	*Complete Waiver or Alteration of Informed Consent section below*	☐	*Complete Waiver or Alteration of Informed Consent section below*
	Obtaining Child Assent		Obtaining Short Form Consent
☐	*Complete the Consent and Assent Processes section below*	☐	*Complete the Consent and Assent Processes section below*

Consent and Assent Processes
Complete a participant group section for each participant group with different consent processes. *Additional tables may generated by clicking the + button to the bottom right of the subsection while its contents are selected. Click in the table below to access the Repeating Section Content Control.*

Participant Group Consent/Assent	Adult Latinos
Type of consent obtained	Written Consent
Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration.	
This study will obtain consent at the following times for the following activities, in the participants preferred language (English or Spanish): **Screening to determine eligibility**. All potential participants will provide informed consent to complete the study screener questionnaire. All potential participants will be told that (1) participation in the screener questionnaire is voluntary, (2) they have the right to refuse to answer any question(s), (3) they have the right to terminate the interview at any time without penalty, and (4) all information disclosed will be confidential and anonymous. The RA will orally provide this information to potential participants being screened by phone or in-person. The RA will then screen potential participants who consent to be screened for eligibility. For potential participants completing the screener online, they will first be taken to an online page that contains the aforementioned information. If the potential participant consents to completing the screener questionnaire, he or she will have to click on a 'I agree button' link that will then take them to the online screener questionnaire.	

Qualitative interview. Persons who are deemed eligible to participate in the study and who accept our invitation to participate in the study will undergo written informed consent. All participants will be provided with written informed consent describing the study design, investigator affiliations and contact information, and study objectives. This consent will also include text informing participants that the qualitative interview is voluntary, (2) they have the right to refuse to answer any question(s), (3) they have the right to terminate the interview at any time without penalty, and (4) all information disclosed will be confidential and anonymous. The interviewer will review the informed consent verbally to ensure that potential participants understand the study objectives and can give their informed consent.

The informed consent process will take place in private setting.

Upload consent forms, script, or letter to IRBaccess.

Waiver of Documentation of Consent	
To approve a waiver of documentation of informed consent, one of the following criteria below must be justified by the researcher. *Only complete the section below if requesting a waiver of documentation of informed consent.*	
☐ Waiver Option 1 A) This study is minimal risk. B) Written consent would not be required outside of the research context	Click or tap here to enter text. *Upload consent form to IRBaccess.*

☐ Waiver Option 2 A) The only record linking the subject and the research would be the consent document B) The principal risk would be potential harm resulting from a breach of confidentiality. C) Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.	Click or tap here to enter text. *Upload consent forms with and without signature lines.* *Include this choice in the informed consent form.* *Articulate the destruction protocol for signed consent forms in the privacy and confidentiality section.*

Waiver or Alteration of Informed Consent	
To approve a waiver of informed consent, all of the following criteria must be justified by the research. Provide a protocol specific justification for each. *Only complete the section below if requesting a waiver of informed consent or alteration of informed consent.*	
The research involves no more than minimal risk to the subjects.	Click or tap here to enter text.
The waiver or alteration will not adversely affect the rights and welfare of the subjects.	Click or tap here to enter text.
The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform	Click or tap here to enter text.

the research if obtaining informed consent is required and not just impracticable to obtain consent).		
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.	Click or tap here to enter text.	
Whenever appropriate, the subjects will be provided with additional pertinent information after participation.	☐	Additional pertinent information would not be appropriate (*e.g.*, no deception).
	☐	Additional pertinent information is appropriate.
		Research that requires alteration of informed consent on the grounds that deception is necessary must complete the deception section below.

Deception	
See IRB Policies and Procedures Section 15 for a description of deception.	
Describe the nature of deception	*Click or tap here to enter text.*
Why is deception required?	*Click or tap here to enter text.*
Describe debriefing procedures	*Click or tap here to enter text.*
☐	Research participants will have the opportunity to withdrawal their data during the debriefing.
Upload debriefing form to IRBaccess.	

Consent Translation	
☒	The study population will likely include participants whose limited English speaking status requires translation of the consent form.
The IRB recommends having English versions of consents approved prior to translation. When available, upload translated documents to IRBaccess.	

See IRB Policies and Procedures Section 6.4.1 for a description of translation procedures.	
☐	The consent documents will be translated by a certified translator.
☒	A non-certified translator will translate the consent documents.
	Describe the translator's qualifications
	All documents have been translated by a bilingual research assistant and reviewed and verified by Dr. Pinedo the PI of the study. Dr. Pinedo is a native Spanish speaker who has worked extensively in Mexico; he can attest to the accuracy of translated documents.
	☒ Documents will be translated, and the research team will attest that the translation is accurate and appropriate.
Upload translated documents and attestation (if required) to IRB Access.	

RISKS AND BENEFITS

Benefits		
Compensation for time and effort is not considered a benefit.		
Benefits to Society		Describe scientific and societal benefit.
		Participants will be informed that their interview and experiences have the potential to help us understand how we can improve the health of Latinos in Austin, Texas.
Direct Benefit	☒	No potential for direct benefits to participants
	☒	Describe potential for direct benefits to participants.
		There is no direct benefit to respondents for participating in the study. Nonetheless, participants may benefit from self-reflection and personal insight involved in answering our interview questions.

Risks	
☐	Greater than Minimal Risk Study
	Complete the Data Safety and Monitoring Plan section below.
Research related risks only pertain to risks associated with procedures required by the study; do not include risks of any procedures that the participant would undergo if not participating in the study.	
Describe the risk(s) associated with the research.	
Overall this study poses minimal risk to participants. The main risks are loss of confidentiality, embarrassment, and discomfort. Participants may experience embarrassment or discomfort associated with responding to interview questions related to migration-related topics and health (e.g., mental health, alcohol and drug use). Thus, there is a possibility that participants may become upset or distressed when talking about certain experiences. However, participants will be informed that they are free to refuse to answer	

any question with no penalty.
Describe the risk mitigation plan
The PI Dr. Pinedo has extensive experience working with Latino migrants in health research and is equipped to take appropriate steps to mitigate any potential risks. Additionally, Dr. Pinedo is of Latino-origin and a native Spanish speaker; he holds the cultural understanding and expertise to successfully implement this project while safeguarding the well being of participants. We will mitigate any potential risks to participants by taking the following steps. All materials (e.g., recruitment flyers, consent forms) will state that we are interested in learning more about the opinions of Latinos in Austin of migration-related issues and their health, including mental health, alcohol use, and drug use. Text that explicitly states that this study will not collect information on immigration status will be included. GRAs will be highly trained on how to deal with distressed participants and to reduce possible discomfort by reading the interview questions in a calm and non-judgmental way. Before beginning the interview, GRAs will explain that all responses entirely confidential, and assure participants that they are free to decline to answer any questions that they do not wish to answer or to stop the interview at any time with no penalty. Additional safeguards will include the availability of phone numbers for crisis and mental health service and substance-use related hotlines if a participant becomes upset or agitated or wants more information about where to go to deal with mental health or substance use. For instance, we will provide, to interested participants, SAMHSA's National Helpline. This helpline is a free, confidential, 24/7, 365-day-a-year treatment referral and information service for individuals and families facing mental and/or substance use disorders. This service provides referrals to local treatment facilities, support groups, and community-based organizations. We will also provide, to interested participants, contact information for local non-profit community organizations that specifically cater and provide resources to immigrant populations (e.g., Casa Marianella, Migrant Clinicians Network). We will update numbers and contact information on a regular basis.

Data Safety and Monitoring Boards (DSMBs) and Plans (DSMPs)	
☐	This study will have a DSMB.
	Describe the DSMB including frequency of meetings, members, data reviewed, and stopping points.
	Click or tap here to enter text.
☐	The study will have a DSMP.
	Describe the DSMP, including what data or responses are monitored, when data is reviewed, and what actions are taken to react to a safety concern.

	Click or tap here to enter text.

Required Consent Disclosures		
Child and Elder Abuse		
Texas law requires that anyone report suspected child/elder abuse or neglect.		
Is it likely investigators could discover information that would require mandatory reporting by the investigators or staff?	☐	Yes, it is likely.
		Include mandated reporting language in applicable informed consent document(s).
	☒	No, it is not likely.
Incidental Findings		
Incidental findings include: genetic markers, concerning test results, disease, suicidal thoughts, unexpected paternity, engaging in illegal activities.		
☐	It is possible that investigators could discover incidental findings or other information about a participant's previously unknown condition.	
	If so, state methods for addressing and reporting incidental findings	
	Click or tap here to enter text.	
	Include incidental report information as applicable in the informed consent document(s).	

Early Withdrawal
List the criteria for withdrawing individual participants from the study (*e.g.*, safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).
Criteria for early withdrawal will include participants who explicitly state that they do not wish to continue with the qualitative interview.
Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.
If a participant decides to no longer participate and is withdrawn from the study, he or she will be provided with any resources (e.g., SAMSHA's national hotline), if interested.
Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.
Click or tap here to enter text.
If any of the above are applicable, include this information in your consent form.

PRIVACY AND CONFIDENTIALITY

Privacy
Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants.
Include information regarding privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.
All research activities involving potential and enrolled participants will take place in private settings. Those completing the screener questionnaire online will be asked to confirm that they are in a private setting before continuing with the survey. Screening of participants via telephone will be conducted in Dr. Pinedo's lab by a GRA; the GRA will confirm that the interested potential participant is in a private setting. When conducting screenings in-person, such as a community event, the GRA will take the participant in a private setting (e.g., a private room) away from others. The qualitative interview will take place in a private setting (e.g., Dr. Pinedo's lab, in a private meeting room at the Austin library).

Confidentiality and Data Security Plan		
Describe how you will protect the confidentiality of data or address confidentiality concerns.		
☒	Identifiers will be coded to protect confidentiality.	Describe how data is coded and where identifiers are stored. Participants will be assigned a random unique study ID to protect their confidentiality. Identifying data will be stored in a password protected file in a secured server. More information is detailed below.
☒	Identifiable data will be destroyed.	Describe destruction plan and timeline Identifiable data will be deleted after recruitment is complete. Audio files will be deleted after interviews are transcribed.
☐	Identifiable data will not be destroyed.	Provide rationale for retaining identifiable data indefinitely. Click or tap here to enter text.
Describe how you will store and secure your data (including length, location, and medium of storage):		
Participants who complete the screener questionnaire will be assigned a study ID. Those who are interested in participating (and meet eligibility criteria) will disclose their first name, email, and telephone number as part of the screener questionnaire. Thus, we will take the following steps to protect the confidentiality and anonymity of interested potential participants. Contact information will be only accessible to the PI and the qualitative interviewer, which will be stored in a password-protected file in a secure computer (fully		

encrypted and firewall protected). Data will be stored in the University's UTBox cloud storage, which provides a secure space to store and share sensitive and confidential data that meets the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA) regulation requirements. Additionally, the screener questionnaire will be programmed using Qualtrics software, which meets the US federal law requirements that establish standards for the privacy and security of health information (i.e., HIPAA). Once a study participant has been recruited and interviewed, participants' contact information will be permanently deleted. Given these precautionary measures, we are confident that breach of confidentiality related to screener data, including interested participants' contact information, will be minimal.

Participants who agree to the qualitative interview will be assigned the same study ID as the screener. However, screener data and qualitative data will be stored separately. The audio recording will be uploaded and kept in a password-protected file in UTBox. Any potentially identifying information (e.g., names) will be deleted or edited out of the transcriptions. Once audio files are transcribed, the audio files will be destroyed. Transcriptions will be coded and analyzed using an assigned research study ID number, which will not include any identifying information. Transcripts will be stored in a separate password-protected file in UTBox. Thus, the risks of loss of confidentiality of participating in this adequately safeguarded and confidential study will be low. Transcripts will be kept up to 3 years to allow for adequate time to conduct analyses.

Data Access					
☒	Study team members	☐	Collaborators	☐	Data coordinating center
☐	Sponsor	☐	Future sharing with other researchers	☐	Other: List.
Describe Data Sharing (If Applicable)					
Only the study team will have access to the data.					

Certificate of Confidentiality		
See IRB Policies and Procedures Section 4.11.5 for a description of a Certificates of Confidentiality.		
☒	The study does not require a Certificate of Confidentiality.	
☐	The study requires a Certificate of Confidentiality.	
	☐	NIH has issued a Certificate of Confidentiality for this study.
	☐	A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.

COMPENSATION AND COSTS

Compensation					
☒	Subjects receive compensation.				
☐	Subject will not receive compensation.				
Total amount of compensation	$40				
Prorating schedule	Click or tap here to enter text.				
When do subjects receive compensation?	Immediately after completing the interview.				
Select the form(s) of compensation					
☒	Cash	☐	Check	☐	Gift Card Type
☐	Course Credit	☐	ClinCard	☐	Other: Describe
☒	Compensation amount and type reasonable for this population for the activities requested of them.				
	The cash incentive is modest to cover participants time.				

Costs			
Select all categories of costs for which participants or their insurance companies will be responsible.			
☒	Participants will have no costs associated with this study		
☐	Standard of care procedures contributing to study data	☐	Research procedures not associated with standard of care
☐	Administration of drugs / devices	☐	Study drugs or devices
☐	Transportation and parking		
☐	Other: Click or tap here to enter text.		

REQUIRED DOCUMENTS

Additional Supporting Documents	
☒	Principal Investigator CV - Required
☐	Faculty Sponsor CV – Required for student PIs
☒	Recruitment Materials
☒	Consent, Parental Permission, and Assent Forms
☒	Measures and Instruments
☐	Sponsor Protocol
☐	Investigator Brochure
☒	Personnel Form

☐	IDE/IND Verification
☐	Supplemental Forms