PROTOCOL TITLE: Duration of Untreated Psychosis and Perceived Barriers to Mental Health Care Among College Students

PRINCIPAL INVESTIGATOR:

Name: Annette S. Crisanti, PhD
Department: Department of Psychiatry and Behavioral Sciences
Telephone Number: 808-895-3240
Email Address: acrisanti@salud.unm.edu

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1.0 Objectives

Increased duration of untreated psychosis (DUP), defined as the time from manifestation of the first psychotic symptom(s) to initiation of evidence-based treatment, is associated with poorer clinical and functional outcomes (Fusar-Poli et al., 2009). Factors associated with longer DUP include perceived barriers to care among those experiencing psychotic-like symptoms and feelings of not being listened to or not being offered the opportunity to make decisions regarding treatment (referred to as shared-decision making). The primary objective of our proposed study is to investigate the association between DUP and perceptions regarding barriers to care and shared-decision making among college students. The secondary objective is to conduct a process evaluation of the inclusion of a screening tool (the Prodromal Questionnaire Brief- PQ-B developed by Loewy et al., 2011) during triage at University of New Mexico Student Health and Counseling Center (SHAC). SHAC implemented the PQ-B August 1st, 2020 to improve quality of clinical services by identifying students at risk of first episode psychosis (FEP) and referring those identified at high risk to coordinated specialty care programs (i.e., Early and CONNECT) in the Department of Psychiatry and Behavioral Sciences, University of New Mexico. The Early Program is a coordinated specialty care program for the young adults experiencing first episode psychosis (FEP) while the CONNECT program provides stepped care to young individuals at clinical high risk (CHR) of developing psychosis.

The specific aims are to:

1. Measure DUP among University of New Mexico (UNM) college students enrolled in the Early or CONNECT Programs in the Department of Psychiatry and Behavioral Sciences and identify other factors that may contribute to longer DUP, such as perceptions relating to barriers to mental health care and shared decision-making. We hypothesize that there will be: (1) a positive association between DUP and the number of perceived barriers to care, and (2) a negative association between DUP and feelings of shared-decision making.
2. Collect process level data related to the implementation of the PQ-B at SHAC, including the number of PQ-Bs completed by students at SHAC; the number of students who meet the cut-off score on the PQ-B; responses to specific items on the PQ-B; and basic demographic and clinical characteristics for those who complete the PQ-B [i.e., age, gender, ethnicity, level of education, feelings of depression as measured by the Patient Health Questionnaire-9 (PHQ-9) and feelings around alcohol use as measured by the CAGE. CAGE stands for Cut, Annoyed, Guilty and Eye based on the four questions in the screening tool that indicates a substance abuse problem. The four questions include: (1) Have you ever felt you should cut down on your drinking? (2) Have people annoyed you by criticizing your drinking? (3) Have you felt bad or guilty about your drinking? And (4) have you ever had a drink first think in the morning to steady your nerves or to get rid of a hangover (eye-opener)? All of these data are collected as part of standard clinical practice at triage among students seeking services at SHAC. Among those students who meet the cutoff, we are also interested in tracking the number of students who are referred to Early and CONNECT and, if not referred, the reasons for not being referred.

2.0 Background

2.1 General Background. Clinical and general population studies on FEP have generated enough evidence to have confidence in three issues. First, the DUP is a strong predictor of outcome, such that current clinical recommendations are <3-6 months

(Compton et al., 2008). Second, in the U.S., individuals are still presenting with DUP on average of two years (Marshall et al., 2005). Third, the reasons for treatment delay are multiple and complex (Apelodoorn et al., 2014). Various classifications have been developed to categorize the factors that contribute to an extended DUP. Compton and Broussard (2011) for example, identified six categories, including: (i) demographic, (ii) premorbid and onset-related, (iii) illness-related, (iv) family-level, (v) societal, and (vi) health system and service level factors.

With the first symptoms of psychosis being most likely to surface around ages 15 to 24, college age young adults are at increased risk of FEP and CHR of psychosis (Kessler et al., 2007; Simon et al., 2017). Studies on the course of schizophrenia indicate that the initial onset of the disorder shows a steep increase during adolescence and young adulthood and then begins to decrease around the age of 25 (Hafner et al., 1993; Sham et al., 1994). Simon et al., (2017) reported a FEP incidence rate of 86 per 100,000 among ages 15-29 compared to 46 per 100,000 among 30-59 across a variety of care settings. There are other environmental risk factors unique to college students that may increase risk of psychosis and contribute to increased DUP. First, attending college can be a stressful time for many students, learning to live independently and handle college level work load. Second, there are higher rates of illicit and prescription drug use among college students. Third, lack of identification of mental health symptoms and/or treatment have surfaced as system-level challenges on college campuses. This contributes to the persistence of mental health problems among students, partly due to the under-resourcing of college mental health services in relationship to needs. Lastly, many college students are in the process of transitioning between adolescence to adulthood and may be less likely to recognize when to seek help or to feel comfortable with accessing services independent of family support.

Screening has been shown to be a valid and reliable way of identifying individuals at high risk of psychosis, and those who have a higher likelihood of transition to psychosis in various contexts for clinical referral (Jarrett et al., 2012; Kline and Schiffman, 2014). When Rietdijk and colleagues screened all individuals between the ages of 18 and 35 entering secondary mental health services for non-psychotic conditions with the Prodromal Questionnaire (PQ) 92-item version, a three-fold higher prevalence of at-risk mental states was detected among the population that was universally screened compared to a population that was referred to a diagnostic center of an early psychosis clinic based on clinical concerns alone (Rietdijk et al., 2012). Studies on the effectiveness of screening for psychosis among college students are scarce. Loewy et al., assessed the rates of self-reported “prodromal” psychotic symptoms and related distress among 1,020 college students at a university in California using the PQ 92-item version (Lowey et al., 2007). Forty-three percent of students reported ≥ 8 items (the suggested cutoff from the initial PQ validation study). The proportion was 2% when the cutoff was modified to ≥8 items rated as distressing (the addition of a *distress* qualifier is intended to improve specificity and thereby reduces the number of false positives). A Chinese version of the PQ-16 was used to determine the prevalence of attenuated psychotic syndrome among 579 college students in China (Chen et al., 2014). Using a cutoff of ≥ six, 9.3% screened positive. Among 49 who completed a follow-up interview, 20 (40%) met the criteria for a prodromal risk syndrome as per the Structured Interview for Psychosis-Risk Syndrome (SIPS) diagnostic criteria.

2.2 Scientific Rational.

Little is known about DUP among college students. Our research will fill this gap. With respect to barriers to care, research has shown that as high as 85% of college-age students do not seek treatment when experiencing a mental health problem (Blanco et al., 2008) despite estimates of mental health problems among college students ranging from 9% to 33% (Hunt and Eisenberg, 2010). Not engaging in treatment for mental health problems can significantly interfere with educational outcome (Eisenberg et al., 2009). There are numerous barriers that hinder access to mental health services, especially for college age young adults. Barriers include, for example, stigma, negative attitudes about treatment providers, poverty, lack of symptom recognition, lack of knowing where to get help, lack of transportation, and feelings of disempowerment (Jennings et al., 2017). Furthermore, in the literature on why people fail to engage or disengage from care, not feeling listened to and not being offered the opportunity to make decisions and collaborate in treatment (O'Brien et al., 2009) have been identified as contributors. Indeed, shared-decision making, an approach to providing person-centered care, has been shown to be a critical factor associated with engagement in coordinated specialty care for first episode psychosis (Hamilton et al., 2018; Heinssen et al., 2014). The goal will be to transfer what we learn about perceived barriers to care and shared-decision making into practice by developing strategies or interventions to reduce the modifiable barriers or increase feelings of shared-decision making so that fewer college students will go without necessary mental health care and specialty services.

While research on screening for first episode psychosis among college students is limited, in general behavioral health-related screening (e.g., for depression, suicidal ideation, alcohol use) among college populations has proven to be effective and to increase access to care (Shepardson et al., 2014). As summarized by Savill et al., "Screening for psychosis may represent a fast, effective solution to identification of early psychosis, without the need for additional expertise" (pg. 689) Savill et al., 2018).

2.3. Contribution to the Literature. Upon successful completion of the proposed research, we expect our contribution to the literature to be preliminary data on DUP among college students and perceptions regarding barriers to receiving mental health care and shared-decision making.

The quality improvement data will also contribute to the literature on screening for first episode psychosis among a college population.

3.0 Inclusion and Exclusion Criteria

3.1 Screening for Eligibility. Screening will be conducted among UNM college students who present to either Early Program or the CONNECT Program, Department of Psychiatry and Behavioral Sciences for an intake assessment. The Early Program is a coordinated specialty care program for the young adults experiencing a FEP while the CONNECT program provides stepped care to young individuals at clinical high risk of developing psychosis. Evidence of psychosis or psychosis risk syndrome will be assessed during the intake visit through a clinical assessment and the Structured Interview of Prodromal Symptoms (SIPS) (Miller et al., 2003) The SIPS will be completed by Early or CONNECT Program clinicians, who are certified in its administration. The SIPS is a structured diagnostic interview and includes the Scale of

Prodromal Symptoms (SOPS); Schizotypal Personality Disorder Checklist, a family history questionnaire and a well-anchored version of the Global Assessment of Functioning Scale. The SIPS takes approximately 60-90 minutes to complete depending on clinical status. Those determined eligible for either program based on the clinical assessment and SIPS will be invited to participate in the study. A copy of the SIPS has *not* been included as attachments as it is a copyrighted instruments. More information about the SIPS can be found on the Prime Psychosis Prodrome Research Clinic website. https://medicine.yale.edu/psychiatry/research/programs/clinical_people/prodome.aspx?organizationId=109519.

It is important to note that patients who enter either program may complete other clinical assessments as part of standard clinical care. While results from these assessments will not be used to determine eligibility for this study, they *may* be used in the proposed study to describe the study population. We will be asking permission to use the data from these standard clinical assessments through the consent process.

3.2 Inclusion and Exclusion Criteria. Eligible participants included in the study will be: (1) 15-30 year-old UNM college students who present to the UNM Early Program or the UNM CONNECT program for an intake, (2) who screen positive for clinical high risk or FEP , and (3) agree to participate in the study. Participants will be excluded if: (1) they are below the age of 15 years old or above the age of 30, (2) are not UNM college students, (3) screen negative for clinical high risk or FEP, (4) refuse to participate in the study, and/or (5) are cognitively unable to provide informed consent as demonstrated by a brief cognitive screen prior to completion of the enrollment interview. Cognitive capacity to consent to research participation will be assessed by the research coordinator using the form included in Attachment 1 - *Evaluation to Sign an Informed Consent Document for Research*.

There are no exclusion or inclusion criteria specific to the PQ-B screening tool implemented at SHAC. The triage process at SHAC has included universal screens for depression, anxiety and substance use for years. As of August 1st, 2020, SHAC extended the universal screening to include risk of psychosis through the inclusion of the PQ-B. Universal screening means that all students who seek counseling services at SHAC complete the PQ-B at triage.

Inclusion of Special Populations.

Adults unable to consent: Those determined unable to provide consent through the brief cognitive screen in Attachment 1 will not be enrolled in the study (see Attachment 1 - *Evaluation to Sign an Informed Consent Document for Research*).

Individuals who are not yet adults (infants, children, teenagers): While we expect the majority of participants to be between 18 and 30, participants as young as 15 may be enrolled into the study. Participants younger than 18 will indicate their assent to participate in the study by signing a child assent form, which will be co-signed by a parent or legal guardian (See consent form). Both the child and the parent/ legal guardian must consent for the participants between the ages of 15 and 17 to participate in the research.

According to UNM main campus enrollment reports, approximately 1% of students are less than 18 years of age. While it will be unlikely that a student less than 18 years of age will complete the PQ-B the NM Statutes stipulate that "*A child fourteen years of age or older has the right to consent to and receive individual psychotherapy, group psychotherapy, guidance counseling or other forms of verbal therapy and information regarding such counseling is confidential. This means that students ages 16 or 17who enter SHAC for counselling will be asked to complete the PQ-B as part of standardized SHAC triage process*

Pregnant women:
Pregnant women are not the focus of this study, and research deals with mental health issues of the young in general.
Students at SHAC may be pregnant when accessing counseling services. As a result, they may complete the PQ-B screening tool. There is no evidence to suggest that the completion of the screening tool will be harmful to pregnant women.
Prisoners: Prisoners will not be included in the study.
Prisoners will not be completing the PQ-B screening tool. Only students seeking counseling services at SHAC will complete the screening tool.

4.0 Study-Wide Number of Subjects

Not Applicable - This is not a multicenter study – see Section 22 for number of subjects

5.0 Study-Wide Recruitment Methods

Not Applicable - This is not a multicenter study – see Section 21 for number of subjects

6.0 Multi-Site Research

Not Applicable - This is not a multicenter study

7.0 Study Timelines

7.1. Duration of an individual subject's participation in the study. Participation in the study is brief. Data will only be collected at one time-point, which will be after the consent process.

7.2. Duration of anticipated time to enroll all study subjects. It is expected that all participants will be enrolled by one year from the start of the study.

7.3. Estimated date for the investigators to complete this study (complete primary analyses)

It is expected that data analyses will be ongoing throughout the study and that final analysis and publication of study data will occur in the 12-months following the end of study enrollment.

8.0 Study Endpoints

8.1 Primary and secondary study endpoints. This is not an outcome study, data will only be collected at one time-point, which will be immediately following the consent process.

8.2 Primary or secondary safety endpoints. NA

9.0 Procedures Involved

9.1 Overview of the study design. The study will use a correlational research design in which we will collect data for each participant only once.

Overview of research procedures being performed and when they are performed. Participants will be recruited among UNM college students and who are determined eligible for the proposed study (see inclusion criteria Section 3.2). Once determined eligible, individuals will be invited to participate in the research. Those who agree to participate will complete the consent process. The research coordinator (Justine Saavedra) or PI (Dr. Crisanti) will be responsible for consenting the individual and data collection. Data will be collected through completion of standardized tools that have all been determined to be reliable, valid and appropriate for the study population (described in 9.3). Data will be collected either through (i) face to face interviews, (ii) phone, or (iii) HIPAA Compliant Zoom Account. These last two options have been put in place to accommodate the social distancing and public health stay at home orders that have been put in place by the NM Governor during COVID. Data will be collected after the consent process. We will aim to collect data at one point in time. However, due to the illness associated with the target population, we may need to split the interview over two time periods. Participants will be provided with a $20.00 amazon merchandise card per hour to standardized compensation across participants. We will always round up. For example: if a participant completes the surveys in 45 minutes we will give them a $20.00 merchandise card; if a participant completes the surveys in an hour and a half we will give them two $20.00 merchandise cards.

9.2 *What data will be collected, including long-term follow-up.* This is not an outcome study so no long-term follow-up data will be collected. Data will only be collected at one-point, following the consent process. In addition to the SIPS, which will be completed by clinicians during the determination of eligibility process, participants will complete the instruments listed below. Noteworthy, is that during the consent process, we will ask students their permission to use their data collected during the determination of eligibility process as well as data from other standard clinical assessments that were conducted on intake. The following instruments will take approximately 2-3 hours to complete.

Demographic Data: Basic demographic data will be collected on each participant, including city of birth, phone number and email (for future contact), current education year, date of birth, sex, gender, race and ethnicity. City of birth and full date of birth are required to obtain a Global Unique Identifier (GUID) in the NIMH Data Archive. A GUID is a subject ID allowing researchers to share data specific to a study participant without exposing personally identifiable information. A copy of the demographic form has been attached.

Structured Clinical Interview for DSM-5 (SCID-5) (First et al., 2015). The SCID-5 Research Version will be used to confirm clinical diagnoses for all participants enrolled in the research study. Only the sub-units for psychosis, mood disorders, substance abuse and trauma-related disorders will be completed. The SCID-5 will be administered by the research coordinator who has been trained in its use and achieved sufficient reliability for research purposes.

Duration of Untreated Psychosis (DUP) will be collected using the Circumstances of Onset and Relapse Schedule (CORS) (Norman and Malla, 2002). The CORS includes

the Topography of Psychotic Episode (TOPE), which together traces the process of seeking treatment by identifying step-by-step contacts with medical and mental health services in the pathway toward contact with early psychosis services. The CORS protocol includes specific questions and follow-up prompts to help determine the onset of prodromal and psychotic symptoms and pathways to care (Attachment 2). The CORS has well established psychometric properties and takes approximately an hour to complete. It will be completed by the Research Coordinator or PI through semi-structured interviews. While participants identified as at CHR for psychosis, by definition, would not yet have had a psychotic episode, we will similarly record onset of attenuated psychosis symptoms in order to better understand barriers and pathways to care for this group.

Barriers to care data will be collected using the Barriers to Seeking Psychological Help Scale (BSPHS) that was developed to measure barriers related to psychological help-seeking for college students (Topkaya et al., 2017). The BSPHS is a self-report survey with established psychometric properties. It includes 17 items measured on a 5-point Likert-type scale ranging from strongly disagree to strongly agree (Attachment #3). The items are summed, and higher scores indicate higher obstacles. We added an open-ended question to the BSPHS that provides an opportunity for participants to identify barriers not addressed, such as cultural beliefs that impede help-seeking. We determined this additional item to be important given the high prevalence of Hispanics, and to a lesser extent, Native Americans among our target population. The BSPHS takes approximately 5 minutes to complete.

Data on shared-decision making will be collected via the CollaboRATE Shared Decision Making in Clinical Encounters PhenX Measure (Barr et al., 2014; Forcino et al., 2018). CollaboRATE is a component of the PhenX Toolkit, a set of well-established and validated measures relevant to biomedical research chosen by consensus of domain experts and sponsored by National Institute of Health. CollaboRATE is self-administered and includes 3-items scored on a 5-point Likert-type scale. Higher scores indicate greater shared decision making. It takes about a minute to complete. A copy of CollaboRATE is attached (#4).

The PQ-B is completed during triage by all students seeking counseling services at SHAC. The PQ-B takes approximately 2-3 minutes to complete and is completed electronically. The PQ-B is a self-report checklist of symptoms associated with psychosis and psychosis risk syndromes. Respondents indicate whether they have had any of the 21 thoughts, feelings and/or experiences in the past month by checking “yes” or “no”. They are asked to exclude any experiences that occurred only while under the influence of alcohol, drugs, or medications that were not prescribed to them. If respondents answer yes to any of the items, they are then asked to indicate how distressing that experience had been on a Likert-type scale ranging from “strongly disagree” to “strongly agree”. Two scores are generated, a total PQ-B score and a total distress score. A copy of the PQ-B is attached.

A counselor at SHAC (Mr. Ruben Zurita) will maintain and share a limited dataset with the research team which will include process level data related to the implementation of the PQ-B at SHAC. The limited data set includes two dates: the completion date of the PQ-B and, for those students who meet the cutoff on the PQ-B, the date of referral to Early and/or CONNECT. These dates are required in the process evaluation to be able to describe the number of PQ-Bs completed and referrals on a monthly basis. A list of the variables that will be included in the limited dataset is attached. The variables

selected will allow us to summarize, at an aggregate level, the number of PQ-Bs completed by students at SHAC; the number of students who meet the cut-off score on the PQ-B; responses to specific items on the PQ-B; and basic demographic and clinical characteristics for those who complete the PQ-B (i.e., age, gender, ethnicity, level of education, presence of co-occurring symptoms of depression as measured by the PHQ-9, and signs for alcohol dependence as measured by the CAGE). Among those who meet the cut-off, the limited dataset will include information on who was referred to Early or CONNECT and among those not referred, the reasons for not being referred.

Mr. Zurita will be responsible for assigning a unique identifier to every student at SHAC and this unique identifier will be entered into the excel spreadsheet that will be shared with the research team. The limited data set will be shared and stored on a shared drive created by HSC IT. The shared drive is located under the secure Psychiatry O: drive. Only Dr. Crisanti, Ms. Saavedra, Dr. McIver (SHAC, Counseling Director) and Mr. Zurita have access to this shared drive. The limited data set excel sheet is also password protected.

A letter from Dr. Stephanie McIver, SHAC Counseling Director supporting this sharing of information has also been attached.

A chart review will also be conducted for those students who were referred to CONNECT and completed a SIPS, but were then determined ineligible for enrollment in the program based on the results. These students were never enrolled in Early or CONNECT and were therefore never eligible to be enrolled in the R34 research project. We will access their EHR to get basic demographics such as sex, gender, race and ethnicity, age at assessment as well as the results of their SIPS assessment to determine why students were deemed ineligible. These limited deidentified data will be entered into a password protected excel spreadsheet.

One of the goals of this study is to determine if the Prodromal Questionnaire-Brief (PQ-B) is an appropriate psychosis screening tool among a college population. We currently have three excel files that have been populated over the study period.

The first excel file (referred to as the triage limited database) is maintained by SHAC. This excel file includes demographic (e.g., gender, age, ethnicity, program year) and clinical information (e.g., the results of the PQ-B, PHQ-9 and CAGE) of all students who complete the PQ-B. To de-identify these data, SHAC assigns unique identifiers to students.

The second excel file (referred to as the secondary phone screen database) is maintained by the Department of Psychiatry and Behavioral Sciences. This excel file includes information on students who are referred to coordinated specialty care (CONNECT/Early) and who contacted the 888-referral number. 237 people in total called the 888-referral number. Of those 237 students, only 57% (n = 136) signed a Release of Information (ROI) which allowed us to look up their demographic and clinical data in the database maintained by SHAC. Because we do not have an ROI for 43% (N = 101), we are missing PQ-B scores, and other valuable demographic and clinical information. As a result, we are unable to fully understand the PQ-B scores among those students who are referred to coordinated specialty care, who ends up completing a secondary screen and who eventually gets enrolled. With missing information on demographic and clinical information (including the PQ-B) score on almost half of those students who reached out

for a secondary screen we will not be able to determine whether the Prodromal Questionnaire-Brief (PQ-B) is an appropriate psychosis screening tool among a college population (a primary goal of this research).

The third excel file includes 21 participants who were enrolled in the research arm of this study through the PQ-B screening. Nine of these 21 participants did not sign an ROI at SHAC to allow access to their PQ-B scores. This is a critical piece of data we need in order to get a full picture of how this screening tool identifies individuals at risk for psychosis.

To address this limitation, we are proposing to use an honest broker process to merge all three databases to\ allow us to fully understand what PQ-B scores indicate clinically within this population. An honest broker is an IRB recommended practice for merging data. We have identified Dr. Tyler Kincaid (statistician and Department of Psychiatry and Behavioral Sciences faculty member) to serve as the honest broker.

Using the master key with client names and unique identifiers for records in the triage limited database, the honest broker will be responsible for merging the three excel files to create a complete dataset. Once completed, the final merged limited dataset- containing both initial screening information from SHAC, secondary screening information from Psychiatry and research data- will be stripped of any identifying information and returned to the study team.

10.0 Data and Specimen Banking

The Early Psychosis data repository will be used to store demographic and clinical information collected from consenting participants who agree to have their information stored in the data repository. This centralized database will store information for future unspecified use. In doing so, this will allow for a less burdensome and more efficient process for collecting information routinely utilized by all researchers. Consent for data to be included in the repository will be obtained during the consent process. Data will be stored for 20 years at which time the electronic repository and the database will be cleared. Re-consent will be attempted in person when those who already consented return for follow-up visits, if we can do so. For those that we can't meet in person, we will re-consent by phone. Those who cannot be contacted, either in person or by phone will be flagged in the repository and data for these individuals will only be kept for 10 years.

The data from the process evaluation will NOT be stored in the Early Psychosis Repository.

11.0 Data and Specimen Management

11.1 *Describe the data analysis plan, including any statistical procedures.* The goals of this study are to (1) measure DUP and perceptions regarding barriers to care and shared-decision making, and (2) conduct a process evaluation of the implementation of the PQ-B (a screening tool to identify risk of psychosis) at SHAC. Descriptive statistics (e.g., means, standard deviations, medians, quartiles) and summary statistics (for the process evaluation) statistics (will be calculated to summarize the characteristics of the student population, to summarize instrument scores, and to summarize process data regarding the PQ-B at an aggregate level . DUP among those with FEP and duration of

attenuated symptoms among those with CHR will be reported in days as a mean and 95% exact Poisson CIs. We will report the mean BSPHS summed scores and 95% CIs.

11.2 Provide a power analysis, if necessary. Not Applicable

11.3 Steps that will be taken to secure the data to maintain confidentiality during storage, use, and transmission. To assure confidentiality all study personnel will be trained and certified in basic human subject's research protections by the UNM HSC CITI Training Program. In addition, the PI will administer ongoing training and supervision of the research coordinator to assure confidentiality and privacy for participants and participant data. Hard copies of the consent will be separated from any hard copies of data and will be stored in a locked file cabinet in the Research Coordinator's office located in the UNM's Department of Psychiatry and Behavioral Sciences, Division of Community Behavioral Health (CBH). CBH is located at 4001 Indian School Street, 87106. The PI also has an office at CBH. Only the PI and research coordinator will have keys to the locked file cabinet. Paper records may be kept for five years following the conclusion of the research. In addition, study records of minors (less than 18 years old) enrolled into the study will be retained until they turn 22 years old. Eventually, copies of the consents and contact information will be scanned and stored on the University's secure O drive, under the Psychiatry folder for an additional five years at which time the information will be permanently deleted. The O drive is a domain share (health.unm.edu) that is setup between groups and users within this domain. Security for the O drive is controlled by login for the domain, with a username and password. Access to the O drive is controlled by UNM admins. As hardcopy data are collected, the research coordinator will transcribe the raw data to an electronic REDCap database. Data may also be collected directly via tablet into REDCAP databases. All REDCAP databases will be password protected and only the PI and research coordinator will have access to the data. Participants will be assigned a participant ID number at the first stage of data processing. The participant ID number will be written at the top of paper symptom scales and only participant ID numbers will be entered into the electronic databases. Data will never be directly linked to participant identifying data. An electronic Access database with links between participant identifying information and ID numbers will be kept on the secure UNM HSC O-drive. Only research personnel will have access to those links.

The limited data set will be shared and stored on a shared drive created by HSC IT. The shared drive is located under the secure Psychiatry O: drive. Only Dr. Crisanti, Ms. Saavedra, Dr. McIver and Mr. Zurita have access to this shared drive. The limited data set excel sheet will also be password protected.

Ms. Saavedra will be responsible for assigning a unique identifier to every student who received a SIPS assessment and did not qualify for enrollment and this unique identifier will be entered into the excel spreadsheet that will be shared with the research team. The limited data set will be shared and stored on a shared drive created by HSC IT. The shared drive is located under the secure Psychiatry O: drive. Only research team members will have access to this shared drive. The limited data set excel sheet is also password protected.

The final merged limited dataset created by the honest broker will be housed under the secure Psychiatry O:drive in a password protected excel sheet. Only the research team will have access to the final dataset.

11.4 Procedures that will be used for quality control of collected data: Double entry data transcription will be used when data are transcribed from paper-and-pencil forms to the electronic REDCap database. Standard REDCap data backup and data protections will be used during the electronic data storage phase.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

Not Applicable: The proposed research does not involve more than minimal risk to subjects.

13.0 Withdrawal of Subjects

13.1 Circumstances under which subjects will be withdrawn from the research without their consent

The only anticipated circumstances for which participants may be withdrawn from the study without their consent is if they indicate cognitive decline during the interview and no longer able to complete the measures.

Data for those individuals who withdraw from the study will continue to be used in the analysis unless participants notify the PI of wanted to withdraw their authorization through writing. Participants will be notified though the consent process of how to cancel their authorization.

13.2 Procedures for orderly termination.

While this will be very unlikely in the proposed study, if the research coordinator or PI are concerned about the participant continuation in the study, they will terminate the participation and explain to the participant the reasons for this action and, that their termination in the study does not impact their receipt of clinical services.

13.3 Procedures that will be followed when subjects withdraw from the research

Participants are free to leave the study at any time, which will be communicated to them during the informed consent process. There is no penalty to participants for leaving the study. They will still be eligible for services in the EARLY or CONNECT programs.

14.0 Risks to Subjects

14.1 Foreseeable Risks

The overall risk to subjects is thought to be very low for this study. Participants will be asked to share private information about their pathways to care and their symptoms that may be uncomfortable for them to discuss and share. Participants may also experience some anxiety or fatigue related to answering the questions in the survey. Participants will be monitored during the data collection process and will be given the opportunity to take breaks or reschedule data collection for another time if needed. The risk of a breach in confidentiality is also minimal. All study data will be de-identified to minimize the risk of breach of confidentiality to participants. As a further protection, participant identifying information and study data will be stored separately. Only the PI and research coordinator will have access to participant identifying information.

14.2 Procedures that may have risks to the subjects that are currently unforeseeable.

Ongoing training and monitoring of participant confidentiality and data safety will occur in weekly staff meeting. If a breach of confidentiality is identified or suspected, the research coordinator will consult with the PI to address the issue, and the PI will report

the breach to the Psychiatry Department Research Committee and to the UNM HSC HRRC.

14.3 Risks to an embryo or fetus should the subject be or become pregnant.
NA - there are no known risks to an embryo or fetus.

14.4 Risks to others who are not subject
NA

15.0 Potential Benefits to Subjects

15.1 Potential Benefits
There are no potential benefits for individuals who participate in this study. Participants will be eligible for services in the Early or CONNECT programs regardless of their participation.

15.2 Indicate if there is no direct benefit. Do not include benefits to society or others.
No direct benefit

16.0 Vulnerable Populations

16.1 Although unlikely, participants may be under the age of 18. They will be protected from the possibility of coercion or undue influence by the inclusion of a parent or legal guardian in the consent process. In addition, parents and legal guardians may participate in the data collection process if they choose to do so. Another population that may vulnerable to coercion or undue influence are patients with diminished capacity or reasoning. Patients who do not have capacity to understand the nature of informed consent will be identified during the consent process and will not be admitted into the study.

17.0 Community-Based Participatory Research

Not Applicable

18.0 Sharing of Results with Subjects

Statistical analysis and interpretation of group data will be made available to participants in community presentations and scientific journals.

19.0 Setting

Determination of eligibility through the SIPS or SCID interviews will be conducted in the EARLY or CONNECT programs clinical offices located in the: (1) Psychiatric Research Building, (2) University Psychiatric Center, or (3) Cimarron Building. The consent process and completion of the instruments described in Section 9.3 above will occur in: (1) a private office at the Psychiatric Research Building, (2) a private office at CBH, or (3) a private location that is convenient for the participant which may include utilizing the clinical offices. At all times, sites for data collection will ensure privacy and confidentiality.

20.0 Resources Available

Research team members will have HRRC-required CITI Training, COI training, and HIPAA Compliance training. Dr. Lenroot, Clinical Director of both the Early and CONNECT programs (added to this study) will provide clinical consultation to the study. All scientific data analysis and publication of results will be done under the supervision of Dr. Crisanti.

Determination of eligibility will occur in Early and CONNECT programs treatment facilities designed to provide adequate privacy for patients and HIPAA-compliant protection of data. Hard copies of data sheets, and consents will be stored in the research coordinators' office in CBH, in a locked file cabinet. The entrance to CBH is also password protected. Copies of the consents and contact information will be scanned and stored on the University's secure O drive, under the Psychiatry folder. The O drive is a domain share (health.unm.edu) that is setup between groups and users within this domain. Security for the O drive is controlled by login for the domain, with a username and password. Access to the O drive is controlled by UNM admins.

It is unlikely that either medical or psychological resources will be required as a result of study procedures. Decisions regarding when and how to administer medical or psychological resources will be the responsibility of the PI, the research coordinator and Dr. Lenroot, Clinical Director of the Early and CONNECT programs.

21.0 Recruitment Methods

Participants will be recruited among UNM college students who are determined eligible for the proposed study (see inclusion criteria Section 3.2). Once determined eligible, individuals will be briefly told about the study by the clinician who conducted the assessment and if he/she is interested in participating in the study they will be connected to the research coordinator. The clinical team will be communicating with the research time when referrals who are UNM students will be coming in for an intake assessment so that they can be approached for consent. The research coordinator or PI will be responsible for providing all of the details of the study to the individual and completing the consent process.

During COVID, these conversations will be conducted either by phone or via HIPAA compliant Zoom Account.

Noteworthy is that we will not be reviewing PHI (i.e. patient name, medical record number, medical history, etc.) to identify eligible subjects.

22.0 Number of Subjects

We expect to enroll approximately 40 students into the study over the study period.

23.0 Provisions to Protect the Privacy Interests of Subjects

Data collection will be completed in offices or a private space maximizing privacy during data collection procedures. The participant's legal guardian may also be present at the time of data collection. During the consent process, we will obtain permission from the participant to access his/her clinical record to access the results of the SIPS or SCID interview and other data from standard clinical assessments. These data will be de-identified before entering them into the REDCAP database. All data will be presented in

aggregate form only in reports or manuscripts. Only the PI and research coordinator will have access to links between study data and identifiers.

24.0 Compensation for Research-Related Injury

Not applicable, this study involves minimal risk to participants.

25.0 Economic Burden to Subjects

Not applicable, there will be no cost of study participation for participants.

26.0 Consent Process

Participant informed consent will be indicated by their signature or that of a parent or legal guardian on an HRRC-approved informed consent instrument. The consent process will occur in: (1) a private office at the Psychiatric Research Building, (2) a private office at CBH, (3) a private location that is convenient for the participant which may include clinical offices, (4) by phone, or (5) via a HIPAA compliant zoom account. At all times, sites for data collection will ensure privacy and confidentiality. The consent process will take place after informing the prospective subject about the study. Through the consent process, participants will learn what will be required of them should they consent to participate in the study. The consent process will also ask participants for their permission to (1) obtain results of assessments that were conducted as part of standard clinical care, (2) keep and use their information collected in the proposed study in a repository for future research that involves early psychosis or shared with other researchers who are studying early psychosis without their additional informed consent (see attached Consent form Appendix for Data Repository), (3) be contacted in the future for participation in other research opportunities around early psychosis. They will also be asked if we can share their de-identified data with the National Institute of Health (NIH) Data Archive as required by the grant. A protocol has been submitted to the IRB for the Early Psychosis Repository. When consent is conducted via phone or HIPAA compliant zoom account, we will need to delay obtaining a documented signature. In this case, we will log this into the non-reportable RNI log and file a “note-to-file” with the consent. We will attempt to get a documented signature as soon as possible.

Once informed consent procedures are completed, study data will be collected.

After a verbal description of the study is given by the research coordinator or the PI and all of the questions posed by the potential participant have been answered, the following will occur to document informed consent in writing:

- The participant or participant’s legal guardian will sign and date the consent document.
- The individual obtaining consent will sign and date the consent document.
- A copy of the signed and dated consent document will be provided to the participant.

If a potential participant who is under the age of 18 is able to demonstrate that they understand the voluntary nature of research participation and the research procedures, the potential risks and benefits involved with the research, the alternatives to participation, and the procedures to follow if they wish to withdraw from the study, they will be allowed sign the informed consent document demonstrating that they have given their assent for participation in the study. Parents or legal guardian will co-sign the document according to the procedures described in the preceding paragraph.

Following approval of modification #3, we will re-consent those who already consented by person if we can do so. For those that we can't meet in person, we will re-consent by phone. Those who cannot be contacted, either in person or by phone will be flagged in the repository and data for these individuals will only be kept for 10 years.

- **Non-English Speaking Subjects**
  All participants must be able to speak and read fluent English in order to be able to review and understand the consent form. The consent form has not been translated to Spanish. We are excluding Spanish speaking subjects because not all of the standardized survey instruments are available in Spanish. Based on Dr. Lenroot's clinical experience with this population over the past three years, 0% of her clients have been only Spanish speaking. That is, they have all been English speaking. However, if we observe that Spanish speaking participants are being excluded once we start participant recruitment, we will: (1) collect Spanish versions of the instruments that are available, (2) translate instruments that are not available into Spanish, and (3) apply for a modification to our protocol to include Spanish speaking subjects.

- ***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***
  NA. There will be no waiver or alteration of the consent process.

- ***Subjects who are not yet adults (infants, children, teenagers)***
  Patients younger than 18-years-old will have the opportunity to participate in the research study. They will indicate their assent to participate in the study by signing a child assent form, which will be co-signed by a parent or other legal guardian.

27.0 Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of <u>de-identified data</u>**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.

3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

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