Mount
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PROTOCOL

Emergency Department Initiated Oral Naltrexone for Patients with Moderate to Severe Alcohol Use Disorder: A Pilot Feasibility Study

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1.0 LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
AUD	Alcohol Use Disorder
CFR	Code of Federal Regulations
CRF	Case Report Form
DSMB	Data Safety Monitoring Board
DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
ED	Emergency Department
EHR	Electronic Health Record
GAD-7	Generalized Anxiety Disorder Screener
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability Act
HSP	Human Subjects Protection
IRB	Institutional Review Board
MAT	Medication Assisted Treatment
MSBI	Mount Sinai Beth Israel
OUD	Opioid Use Disorder
PDDS	Perceived Devaluation Discrimination Scale
PHQ-9	Patient Health Questionnaire
PI	Principal Investigator
PROMIs	Patient-Reported Outcome Measurement Information System
QA	Quality Assurance
RN	Registered Nurse
SAE	Serious Adverse Event
SBIRT	Screening, Brief Intervention and Referral for Treatment
TLFB	Time-Line Follow-Back
VAS	Visual Analogue Scale
WHO	World Health Organization

2.0 STUDY SYNOPSIS

This study will recruit Emergency Department (ED) patients with moderate to severe alcohol use disorder (AUD) who are interested in initiating medication assisted treatment (MAT). The study is split into two phases. The first phase (N=10) will use implementation science strategies to strengthen existing non-targeted ED based AUD screening program and optimize feasibility, acceptability, and linkage pathways. The second phase (N=20) will incorporate lessons learned from phase 1 to initiate ED patients on MAT for AUD in the form of oral naltrexone. The primary outcome for both phase 1 and phase 2 is engagement in comprehensive addiction treatment at 14 and 30 days post enrollment.

2.1 Study Design

Overview

The study will be comprised of two components outlined below:

1) Site Implementation Component

In this component implementation science strategies will be used to strengthen existing non-targeted ED based AUD screening program and optimize feasibility, acceptability and linkage pathways. Three specific aims are to, 1) optimize registered nurse (RN) driven non-targeted alcohol use screening supplemented with secondary screening using DSM-5 criteria for AUD and an SBIRT (screening, brief intervention and referral to treatment) intervention administered by trained staff. 2) During a 3-month period, use continuous quality improvement methods to decrease the time for completion of AUD screening to an interval that is acceptable to ED patients and ED providers and 3) Assess willingness to initiate oral naltrexone among ED patients with moderate to severe AUD. Ten (10) patients will be enrolled in phase 1.

2) Oral Naltrexone Feasibility Component

In this component we aim to assess the feasibility of initiating treatment in ED patients with moderate to severe AUD on oral naltrexone, an evidence based and accepted standard of care treatment for AUD. Specifically, 1) over an 8-month period we aim to identify 20 patients with moderate to severe AUD eligible and interested in immediate initiation of oral naltrexone. Consenting patients will be receive a standard SBIRT intervention and be provided with immediate oral naltrexone initiation in the ED with a 14-day starter pack at the time of ED discharge. All participants will receive facilitated linkage to comprehensive out-patient care. 2) We will evaluate the impact of immediate ED initiated oral naltrexone with the primary outcome being engagement in comprehensive addiction care at 14 and 30 days post enrollment. Secondary outcomes include medication adherence, changes in daily alcohol consumption, number of heavy drinking days, hospital admissions and ED utilization, transition to long-acting injectable naltrexone and alcohol craving. 3) Lastly, we will collect data on recruitment and attrition rates, as well as means and standard deviations for key measures that will be needed to plan a definitive randomized controlled trial of ED-initiated oral naltrexone.

3.0 INTRODUCTION

3.1 Background and Rationale

Alcohol use disorder (AUD) is the most common disorder of addiction in the United States (US) affecting more than 14 million individuals in 2019.[1] The physical, psychological and health costs of alcohol use disorder and heavy alcohol use (binge drinking on 5 or more days in the past 30) are unparalleled.

From 2006 to 2010 alcohol associated deaths in the US approached 88,000 or 9.8% of all US deaths.[2] Costs to the US healthcare system in 2010 from alcohol related conditions were $249 billion.[2] While the physical, mental and psychological impacts of AUD have recently been overshadowed by increased rates of opioid use disorder (OUD) and opioid related deaths, AUD remains the largest and most costly substance use disorder by several orders of magnitude.

Despite the availability of medication assisted treatment (MAT) for AUD, fewer than 9% of eligible patients are prescribed one of the four FDA approved medications for AUD treatment (oral and long-acting naltrexone, disulfiram and acamprosate).[2] Numerous barriers to the expansion of MAT for AUD to the out-patient setting have been identified including AUD pharmacotherapy complexity, limited experience and knowledge with AUD MAT and negative attitudes towards patients with AUD.[3, 4] These barriers mirror those for out-patient medication initiation for patients with OUD.[5, 6] EDs have become a major site of expansion for medication initiation in patients with OUD and there is good reason to believe that, having demonstrated the operational capacity and experience with pathways and medications relevant to treatment implementation for OUD, that EDs could successfully implement medication treatment for AUD.[7-12] Of the four medications for AUD, oral naltrexone is a prime target for initiation in the ED for several reasons: 1) Oral naltrexone it is relatively safe, having a serious adverse event rate similar to placebo in multiple clinical trials.[13] 2) It is easy to administer. 3) It does not require a period of abstinence prior to initiation and 4) can used to bridge to the long acting injectable formulation.

Traditionally, EDs have provided 'safety net' care for those who do not receive care elsewhere.[14-16] These "hidden populations" consist of individuals who are not engaged in primary care, are underserved, uninsured, and belong to minority groups.[16-18] Expanding the AUD treatment initiation options for these populations in the ED could have a major contribution to population health. The investigators have already developed a successful program for buprenorphine initiation in ED patients with OUD and will leverage the lessons learned from that program in this proposal. Given the need to expand access to and engagement in AUD treatment, the promise of using EDs as an initiation and linkage platform to successfully reach otherwise difficult to reach at risk persons, and ED patients' willingness to start medications for AUD, our Aims are to:

3.2 Innovation

While MAT for AUD with oral naltrexone has long been established as an effective treatment for patients with moderate to severe AUD, uptake has been poor. This study is innovative in that it evaluates the feasibility of expanding the pool of potentially eligible patients for MAT with oral naltrexone by identifying the patients in the ED and initiating treatment. This pathway builds upon a plethora of recent research with OUD demonstrating that ED initiated treatment increases the likelihood of patient remaining engaged in comprehensive addiction care at 30 days post-ED visit and beyond.

3.3 Public Health Impact

Traditionally, EDs have provided 'safety net' care for those who do not receive care elsewhere.[15-17] These "hidden populations" consist of individuals who are not engaged in primary care, are underserved, uninsured, and belong to minority groups.[17-19] Expanding the AUD treatment initiation options for these populations in the ED could have a major contribution to population health.

4.0 SPECIFIC AIMS AND HYPOTHESIS:

Aim 1: Implementation Aim 1: Strengthen existing non-targeted ED based AUD screening program and optimize feasibility, acceptability and linkage pathways.

1a. Optimize registered nurse (RN) driven non-targeted alcohol use screening supplemented with secondary screening using DSM-5 criteria for AUD and an SBIRT intervention administered by trained staff.
1b. During a 3-month period, use continuous quality improvement methods to decrease the time for completion of AUD screening in 10 ED patients to an interval that is acceptable to ED patients and ED providers.
1c. Assess willingness to initiate oral naltrexone among ED patients with moderate to severe AUD.

Aim 2: Feasibility Aim 1: Over an 8-month period we aim to identify 20 patients with moderate to severe AUD eligible and interested in immediate initiation of oral naltrexone. Consenting patients will be receive a standard SBIRT intervention and be provided with immediate oral naltrexone initiation in the ED with a 14 day starter pack at the time of ED discharge. All participants will receive facilitated linkage to comprehensive out-patient care.

2a. Evaluate the impact of immediate ED initiated oral naltrexone with the primary outcome being engagement in comprehensive addiction care at 14 and 30 days post enrollment. Secondary outcomes include medication adherence, changes in daily alcohol consumption, number of heavy drinking days, hospital admissions and ED utilization, transition to long-acting injectable naltrexone and alcohol craving.
2b. Collect data on recruitment and attrition rates, as well as means and standard deviations for key measures that will be needed to plan a definitive randomized controlled trial of ED-initiated oral naltrexone.

5.0 STUDY DESIGN

5.1 Study Timeline

	PROJECT TIMELINE	Development Phase			Implementation Phase			Feasibility Phase								Completion Phase			
2	Months	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18
3	Start-up Activities	Protocol, IRB, Training																	
4	Implementation Facilitation				First enrollments														
5	Trial Recruitment							Enroll 20 participants											
6	Patient follow up				Follow-up 14 and 30 days														
7	Study close out activities															Enrollment closes	Data reconcilation and analysis, manuscript preparation		

6.0 STUDY SETTING

6.1 ED Characteristics

This is a single site study taking place in the Emergency Department of Mount Sinai Beth Israel Medical Center.

The Beth Israel Department of Emergency Medicine was established an independent academic ED in 1989. After the merger with the Mount Sinai Health System in 2013 the ED was integrated into the larger Mount Sinai Health System and is today known as the Mount Sinai Beth Israel (MSBI) Department of Emergency Medicine. There are 29 full-time core faculty actively engaged at the local, state, national and international levels as clinical, educational, administrative, and research experts in emergency medicine.

MSBI is the second most active Emergency Department in respect to research activities in the health system after MSH.

6.2 Physical Space

The Emergency Department at MSBI is comprised of 3 main divisions: Pediatric Emergency Service, Adult Acute Care, FastTrack for lower acuity patients; all located in adjacent areas on the first floor of the Dazian Pavilion at the corner of 1st avenue and 16th street in Manhattan, New York. The Department also runs a separate Urgent Care Facility at 10 Union Square, part of the Mount Sinai Downtown out-patient clinic system. With more than 30 medical practices this center Is a “hospital without beds” where patients care receive both primary and specialty care. The academic offices of the Department of Emergency Medicine are located in the adjacent Silver building. The Research division also has dedicated space in the Emergency Department for the research coordinators. All members of the research team who are housed in this area are outfitted with a workstation or laptop with network access to all MSBI computing services.

6.3 Clinical Services – Mount Sinai Beth Israel

An 856-bed teaching hospital founded in 1889 on Manhattan’s East Side, Mount Sinai Beth Israel (MSBI) is notable for its unique approach to combining medical excellence with clinical innovation. The hospital also has significantly advanced its commitment to community-based ambulatory care and expanding patient access to primary and specialty care. Built in 2010, the MSBI ED has approximately 90,000 annual patient visits. ED demographics are as follows: 51% male, 26% white, 18% African American, 20% Latino, 5% Asian, and 31% more than one race. The payer mix is 36% Medicaid, 11% uninsured, 26% Medicare and the remainder with private or other governmental plans.

7.0 IMPLEMENTATION COMPONENT

7.1 Primary Aim:

To strengthen existing non-targeted ED based AUD screening program and optimize feasibility, acceptability, and linkage pathways.

7.2 Secondary Aim:

To assess willingness to initiate oral naltrexone among ED patients with moderate to severe AUD.

ED items for implementation aim received from quality improvement:

1) Number of ED visits for patients with an ICD10 code related to alcohol abuse who have a completed RN alcohol screen
2) Number of ED visits for patients with an ICD10 code related to alcohol abuse who have a completed AUDIT-C
3) Number of ED visits for patients with an ICD10 code related to alcohol abuse who receive a referral for outpatient treatment

ED items for implementation aim received from potential study participants:

1) Number of ED patients approached for study participation
2) Percentage of those approached who agree to study screening
3) Percentage of ED patients who complete behavioral screen (DSM-5)

ED items for implementation aim received from enrolled participants:

1) Percentage of enrolled participants who complete medical screening
2) Length of time to complete medical screening procedures
3) Percentage of participants who meet both behavioral and medical criteria for MAT
4) Percentage of patients that indicate a willingness to initiate MAT for AUD
5) Percentage of enrolled participants who accept referral for out-patient treatment
6) Percentage of enrolled participants engaged in formal addiction care at 14-days post index visit
7) Satisfaction with the screening program

8.0 PATIENTS AND METHODS

8.1 Patient Population

The target population will be the lower Manhattan community that Mount Sinai Beth Israel (MSBI) services. This community is predominantly made up of the Lower East Side, East Village, Two Bridges, Chinatown and Stuyvesant Town/Peter Cooper Village.[19] The collective population of these neighborhoods is over 185,000. Within this geographic area, the community living between Bowery and the East river to the west and east respectively and 14th street and the Brooklyn Bridge to the north and south, has some of the oldest and poorest residents in New York City.[20] Based on census data almost 35% of the population is foreign born with 65% of those emigrating from Asia, 26% emigrating from Latin America, and 11% from Europe.[20] Median household incomes in these neighborhoods remain substantially lower than the rest of NYC with some communities, such as Two Bridges, where the median household income is more than 60% below the NYC median.[20]

8.2 Inclusion / Exclusion Criteria

INCLUSION CRITERIA

1) Emergency Department patients 18 years of age or older
2) Treated in the ED during screening hours
3) Moderate to severe AUD as determined by DSM-5 criteria
4) Able to speak and understand English
5) Medically stable for an interview as determined by their primary ED provider
6) Willing and able to consent to study participation
7) Two points of contact available for follow-up

EXCLUSION CRITERIA

1) ED patients younger than 18 years of age
2) Medically or psychiatrically unstable as determined by the ED provider
3) Unable to speak or understand English
4) Unable to provide consent for study participation
5) Past year opioid dependence
6) Urine drug screen positive for opioids
7) Current or anticipated need for opioid medications for pain
8) Anticipated surgical procedure within 14-day of ED visit
9) Serologic evidence of liver disease (LFTs 3X normal) within 7 days of enrollment
10) Cirrhosis either by PMH or self-report
11) Pregnant or breastfeeding
12) Lacking contact information for follow-up
13) Requiring in-patient admission for medical or psychiatric reasons
14) Patient receiving a sexual assault forensics exam (SAFE)

15) Patient suspected of having COVID-19
16) Patient is actively suicidal or homicidal
17) Previously enrolled in either the implementation or feasibility phase of the study
18) Be a prisoner or in police custody at the time of the index ED visit
19) Be currently (anytime within the last 14 days) enrolled in formal addiction treatment, including by court order.
20) In the investigators opinion patient would be unable to comply with study directions and follow-up
21) Patient being admitted for inpatient detox
22) Patient in CPEP

8.3 Number of Study Subjects

In 2020, the Mount Sinai Beth Israel Emergency Department recorded 4,384 patient visits with a discharge diagnosis (ICD10 code) related to alcohol abuse. A single health educator (HE), working 8-hour shifts, 5-days a week will be able to screen 10-15 patients a day. This is approximately 2.5-5% of the daily adult ED volume. Given the number of ED visits related to alcohol use disorder we believe we can easily recruit 30 patients (10 in the implementation phase and 20 in the feasibility phase) to complete the study in 1 year.

9.0 STUDY DESIGN AND PROCEDURES

9.1 Screening and Recruitment

The study team will use both targeted and non-targeted recruitment methods.

Patients will only be recruited while they are in the ED. Research Assistants (RAs) assigned to the study will work various shifts including, days, evenings and weekends to ensure success with enrollment. The RA will identify patients seen in the ED by reviewing the EHR track boards and by provider referral.

Study staff will review the ED tracking board to identify patients with chief complaints that might indicate eligibility. This would include patients presenting to the ED for complaints related to alcohol use including intoxication or seeking alcohol use treatment or detoxification. For track board screening, study personnel will have to view the following identifiable information:

- Date of Birth
- Age
- Chief Complaint

A HIPAA waiver request will be submitted to review this limited information for screening purposes only. This information will not be recorded.

The RA will keep a log of all patients screening and excluded and the reasons for exclusion.

If a patient is deemed potentially eligible based on tracking board review, study staff will approach the patient's ED provider to ascertain if the patient is medically and psychiatrically stable to be approached for potential study participation. Only after obtaining permission from the patient's ED provider will the patient be approached for study participation.

Study staff will approach the patient, introduce themselves, and ask for <u>verbal consent</u> to complete a set of screening assessments that includes questions about alcohol use embedded in a general health screener that also includes questions about safety, tobacco and opioid use in the last 30 days.[21, 22] Embedded

questions have been noted by the World Health Organization (WHO) to improve the reliability of self-reported behavior. As part of the verbal consent process patients will be informed that the screening questions are to assess their eligibility for a study on oral naltrexone for patients with moderate to severe alcohol use disorder. Patients will be told they are free to decline screening and can opt-out at any time. They will also be informed that none of the screening information collected could be used to identify them and that their answers to the screening questions are anonymous. We will not be collecting any identifiable information until the patient is found to meet eligibility criteria and signs written informed consent. We will ask for a modification of written consent for screening purposes.

If alcohol use is reported in response to the general health screener the RA will perform a structured diagnostic interview with questions based on the DSM-5 criteria to evaluate for the presence of moderate/severe AUD. Potential study patients who do not meet criteria for moderate/severe AUD will not be asked to participate but will be given referrals as per existing ED protocols. Those who meet criteria for moderate/severe AUD will be informed that they may qualify for the study. They will then be asked to provide a urine sample to check for opioids. If the urine test is negative for any opioid and the patient indicates he/she is able to provide contact information for 2 separate reliable contacts (in addition to their own) and the patient meets all eligibility criteria on the Patient Eligibility Summary form (Appendix 1), patients will be offered participation and informed consent will be obtained. Of note, we will not be asking the patients specific information about their contacts, only if they have them. Only after written informed consent for study participation will participants be asked to provide the specific contact information. Patients whose point of care urine test strips are positive for fentanyl only, which are not approved for clinical use will not be considered eligible for study participation. Women of childbearing age will have a pregnancy test performed on this urine sample to assess for study eligibility.

9.2 Informed Consent Procedures

We will use the Icahn School of Medicine PPHS as the IRB of record for this study and will comply with all necessary informed consent requirements. Only IRB-approved Informed Consent documents and HIPAA disclosure allowing study access to protected health information in the patient's ED medical record will be used.

In addition, potential participants will be instructed concerning the importance of full and accurate disclosure. Initial screening questions will be asked with verbal consent however, all eligible study patients will be asked for written consent to participate using the IRB-approved forms.

As part of the consent process we will also ask for consent for health records matching.

9.2.1 Consent for records matching:

As part of standard clinical care all patients presenting to any of Mount Sinai's Emergency Departments are asked to provide authorization for Mount Sinai health care providers to access their medical records via the health information exchange or HEALTHIX. This authorization will continue to be collected by clinical staff as per the standard operating protocols of the Emergency Department.

Individuals will be able to participate in the study whether or not they consent to HEALTHIX matching.

In order to minimize the possibility of undue influence, potential subjects will be informed that participation is voluntary, refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may cease participation at any point.

9.3 Study Procedures

After signing written informed consent study participants will undergo phlebotomy to assess the medical eligibility criteria for oral naltrexone initiation. This includes a measurement of Liver Function Tests (LFTs). Patients with LFTs 3X normal will not be eligible for ED naloxone initiation but will continue in the study.

Enrolled participants will also be asked to complete a number of validated and study team developed measures including:

1) Locator form with additional demographics (Appendix 2)
2) Stigma scale (Appendix 3)
3) Crime and justice assessment (Appendix 4)
4) Daily substance use report (timeline follow-back methodology) (Appendix 5)
5) Health services utilization report (Appendix 6)
6) Health status report (Appendix 7)
7) HIV risk behaviors report (Appendix 8)
8) PROMIS 29+2 Profile (PROPr) (Appendix 9)
9) Patient satisfaction (Appendix 10)
10) Craving scale (Appendix 11)
11) Generalized Anxiety Disorder Screener (GAD-7) (Appendix 12)
12) ED Health Quiz (Appendix 13)
13) DSM-5 for AUD (Appendix 14)
14) Patient Health Questionnaire (PHQ-9) (Appendix 15)
15) Healthix authorization (Appendix 16)

The RA will then complete the ED Visit Review (Appendix 17).

9.4 Daily Assessments

On a daily basis (excluding the 14 and 30 day follow-up assessment visits) the patient will be asked to complete a craving scale and daily substance use report. These scales will be completed using a Qualtrics survey sent to the patient's electronic device (phone, computer). For patients without a device capable of receiving and completing electronic surveys these daily assessments will be performed over the phone.

9.5 Follow-up

All patients will be given follow-up referrals at the Addiction Institute of Mount Sinai (AIMS) within 14 days of their ED visits. Follow-up study assessments will occur at 14 and 30 days post ED visit. As much as possible study assessment visits will be scheduled to correspond with clinical addiction medicine visits. For patients that have a clinical addiction medicine visit at 14 and/or 30 days post study enrollment the RA will meet the patient at their clinic visit to complete the follow-up study assessments. For patients that do not have a clinical addiction medicine visit coinciding with the 14 and/or 30 day follow-up assessments those assessments will be performed over the phone.

Follow-up assessments will include:

1) Crime and justice assessment
2) Daily substance use report (timeline follow-back methodology)
3) Health services utilization report
4) Health status report
5) HIV Risk Behaviors Report
6) PROMIS 29+2 Profile (PROPr)

7) Patient satisfaction
8) Craving scale
9) Generalized Anxiety Disorder Screener (GAD-7)
10) Patient Health Questionnaire (PHQ-9)

Assessment of engagement in formal addiction treatment on days 14 and 30 will be based on direct contact with the treatment provider/program provided by the participants and will be documented on the treatment facility survey (Appendix 18). If the facility if outside of the Mount Sinai Health System, a signed release authorization form (Appendix 19) will be sent. Study participants will be provided with a "study card" indicating their participation in the study and their use of oral naltrexone. The study card will also list the study teams contact information. Printed reminders for the follow-up will be given to the study participant prior to discharge. In addition the RA will send a reminder in the mail/text/email or social media (based on the study participant's preference) about 7 days prior to the scheduled follow-up assessment with an additional reminder phone call the day before the scheduled follow-up assessment.

9.6 Compensation

Because of the expected difficulty of maintaining high follow-up rates in the study population, adequate compensation for time and inconvenience is critical. Compensation of a $50 gift card will be distributed in-person for completing the enrollment process at the initial ED visit. This card will be reloaded with an additional $50 after successful completion at each of the follow-up assessments at 14 and 30 days post-enrollment visits.

For each daily assessment completed participants will receive $5 which will be uploaded to their gift-card at each follow-up assessment time-point (14 and 30 days). If the participant completes all daily assessments (days 1-13 and 15-29) the total additional amount they could receive would be $140. Participants completing enrollment, both 14 and 30 day follow-ups, and all daily assessments would receive total compensation of $290.

9.7 Standard Intervention for all Participants: SBIRT

Screening, Brief Intervention, and Referral to Treatment (SBIRT) is an evidence-based public health approach to identify patients who use alcohol and/or drugs at risky levels and referring them to substance use disorder treatment. SBIRT begins with screening all patients for substance use disorders.[23, 24] This screening is currently mandated by NYS public health law (Part 405.9 of Title 10).[25, 26] At MSBI the regulatory requirement for screening is accomplished using the two question screener developed by Smith, et als. built into the Epic RN primary assessment which is reproduced below.[27, 28]

The nurse will complete a primary assessment for each patient by asking the following questions:
1. How many times in the past year have you had 4-5 or more drinks in a day?
2. How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?

An answer of 1 or greater for either question is considered as a positive screen. For patients with AUD study staff will then complete additional screening using DSM5 criteria for AUD to determine if the patient has AUD and the level of severity. After a patient is screened and determined to have AUD, study staff will initiate a brief intervention where the patient is told their screening score and they have a discussion with the patient about how important the patient views changing their alcohol use to be (Appendix 20), how confident they are that they can change their behaviors (Appendix 21), and their readiness to change those behaviors (Appendix 22). The brief intervention is a good time to ask the patient about their goals so you

can offer referrals that will help them best reach their stated goals. Finally the patient will be offered a referral to treatment which could include inpatient or out-patient services.[29]

10. STUDY ASSESSMENTS

10.1 Overview:

The baseline and follow-up assessments for this study attempt to balance the benefits of comprehensive data collection against the feasibility of collecting data in often chaotic and pressured environment of the Emergency Department.[30] A cumbersome assessment process is also likely to impede the successful completion of the study through an adverse effect on recruitment nor would it model real-world clinical practice. If this intervention is to be successful it must not only be shown to be effective but also feasible and pragmatic. Excluding collection of a study patient participant characteristics and locator information, the patient's baseline data will include a brief assessment of health status, healthcare utilization, past 7-day alcohol and drug using Time-line Follow-Back (TLFB) method,[31] use of other substances the HRQol[32] and other data necessary to measure costs. The total expected time burden for the screening assessments is 30 minutes. Assessments collected at 14 and 30 days post study enrollment will be similar. Daily assessments should take no longer than 4 minutes.

10.2 Table: Schedule of Study Activities and Assessments by Study Time Period

Instrument/Activity	Time	Done by	Study Assessments					
			Screening	Enrollment	Day 1-13 Assessment	14-Day Assessment	Day 15-29 assessment	30-Day Assessment
			(Index ED Visit, Day 0)		Qualtrics or phone	Phone	Qualtrics or phone	Phone
ED Health Quiz	2'	RA	X					
DSM-5	5'	RA	X					
Urine Drug Screen	5'	RA	X					
Patient Eligbility Summary	2'	RA	X					
Written Informed Consents	10'	RA		X				
Demographics	5'	RA		X				
Locator Form	5'	RA		X		X		
Other Substance Use	1'	RA		X		X		X
Cannabis Assessment	2'	RA		X				
Timeline Follow-Back (TLFB)	10'	RA		X		X		X
Health Services Utlization (Inpatient and Outpatient)	6'	RA		X		X		X
PHQ-9	3’	RA		X		X		X
GAD-7	1’	RA		X		X		x
Health Status Report	2’	RA		X				
HIV Risk Behavior	5’	RA		X				
Stigma Scale	3'	RA		X				
Health-Related Quality of Life (HRQol)	2'	RA		X		X		X
Crime and Criminal Justice	1'	RA		X				
PRISE (Appendix 31)	3’	RA				X		
Alcohol Craving	2'	RA/Participant		X	X	X	X	X
Daily Alcohol Intake	2'	Participant			X		X	
Satisfaction Scale	3'	RA		X		X		X
Total Duration in Minutes			14'	58'				
Healthcare Visits Logistics	3'	RA						X
Total Duration in Minutes					5'	33'	5'	26'
RA/PI Assessments								
ED Visits and Hospitalizations		RA						X
Engagement in Treatment Survey		RA						X
Process Outcome		RA						X

Serious Adverse Event (Death)	X
Protocol Deviations	X

10.3 Pre-Enrollment (Screening) Assessment Phase

10.3.1 ED Health Quiz

Individuals will meet with an RA to be evaluated for study eligibility. This assessment will be conducted after verbal consent, and before enrollment into the study. It will include questions about alcohol and opioid use in the past 30 days embedded in a general health and substance use screening.

10.3.2 Assessment of AUD: Questionnaire Based on DSM-5[33]

The DSM-5 criteria are assessed during the screening period to determine a current diagnosis of moderate or severe alcohol use disorder. The assessment will be completed electronically and will be automatically scored.

10.3.3 Urine Drug Screen (Toxicology Testing)

Urine testing will be performed for the presence of the following drugs: opioids, oxycodone, benzodiazepines, cocaine, methamphetamine, amphetamine, ecstasy (MDMA), marijuana (THC), barbiturate, methadone, buprenorphine and fentanyl. The urine drug screen is collected during the screening phase of the initial ED visit. The fentanyl point of care test strip is being used for research purposes only. Urine testing supplies will be purchased for this study and kept separate from the general ED stock.

10.3.4 Patient Eligibility and Inclusion/Exclusion

The Patient Eligibility and Inclusion/Exclusion form collects information regarding eligibility during the screening phase, before written informed consent is obtained. This includes an initial discussion about the availability of two alternate contacts in addition to the participant. Prior to signing consent patients will only be asked if they have two points of additional contact and not the specific information for those contacts.

10.3.5 Informed Consent and Research Authorization (HIPAA) Forms

Only patients who continue to meet study eligibility criteria will be allowed to continue to the enrollment phase.

10.4 Enrollment Assessments

10.4.1 Demographics

The demographics forms collect information about demographic characteristics of the study participant, including age, gender, cultural/ethnic group, education level, marital status, and type of insurance. This form is completed at enrollment only.

10.4.2 Locator Information Form

A locator form is used to obtain information to assist in finding study participants during the 14 and 30 day assessment period. The form collects contact information including the participant's current address, email address, and phone number. In an effort to facilitate locating participants if direct contact efforts are unsuccessful, address and phone number of family/friends who may know how to reach the participant are also collected. This information will be collected at enrollment and updated at each follow-up visit. Locator information will not be used in data analysis.

10.4.3 Other Substance Use

Select questions from the ASSIST-lite (Appendix 23) will be used to assess severity of drug use problems over the last 3 months and will be asked at enrollment only. Questions related to alcohol use have been eliminated to avoid duplication.

10.4.4 Cannabis Assessment (Appendix 24)

This questionnaire is an 8-item measure that is used to assess cannabis use in the past 12-months. This questionnaire is collected at enrollment only.

10.4.5 Timeline Follow-Back (TLFB)

The Timeline Follow-back procedure will be used to elicit the participant's self-reported use of alcohol and other substances.[31, 34] At enrollment, substance use is reported by the participants for the 7-day period prior to the index ED-visit. At 14 and 30 day follow-up assessments, substance use is again reported for the 7 days prior to the visit.

10.4.6 Health Service Utilization Inpatient and Outpatient Health Services Utilization[35]

A brief, structure interview regarding health care utilization will be used, which collects information on the type and amount of services received. This includes ED visits, hospitalizations and primary medical care visits. This form is collected at enrollment, 14 and 30 days post-enrollment.

10.4.7 Health Status

We will collect information on HIV and Hepatitis C status, HIV risk, and psychological health (**PHQ-9**).[36] The **Data Harmonization Measure** is an HIV Risk Behavior Scale. The PHQ-9 is used to assess depressive symptoms including suicidal ideation. If the participant responds to "Thoughts that you would be better off dead, or of hurting yourself in some way" other than "Not at all", it will prompt a clinician assessment for suicide risk. Also included in the health assessment will be the **GAD-7**[37], a brief 7-question survey to assess the degree of the participant's anxiety. All health status scales are collected at enrollment, 14 and 30 days post enrollment.

10.4.8 Stigma Scale

The 12-item Perceived Devaluation Discrimination Scale (Link, 1982; Link et al., 1991) will be used to assess the extent to which a person believes that other people will devalue or discriminate against someone with a mental illness. This is collected at enrollment, 14 and 30 days post enrollment.

10.4.9 Health-Related Quality of Life (HRQol)

The HRQoL (Appendix 25) will be measured using the Patient –Reported Outcomes Measurement Information System (PROMIS).[32] PROMIS domains include Cognitive Function – Abilities, Depression,

Fatigue, Pain, Interference, Physical Function, Sleep Disturbance, and Ability to Participate in Social Roles and Activities. Levels for each domain range from no problems over light, moderate and severe problems to extreme problems. This is collected at enrollment, 14 and 30 days post enrollment.

10.4.10 Crime and Criminal Justice

This form captures data on incarceration, recent crimes, and recent contact with the law and is collected at enrollment, 14 and 30 days post-study enrollment.

10.4.11 Alcohol Craving

We will use a standardized craving scale to assess craving to use alcohol. This will be asked daily for days 0-30 via Qualtrics or phone.[38, 39]

10.4.12 Daily Alcohol Intake

Daily alcohol intake will be assed with a short survey. This will be asked daily on days 2-13 and 15-29 via Qualtrics or phone.

10.4.13 Satisfaction Scale

A short 3uestion satisfaction scale will be used to measure satisfaction with the screening and linkage process. This will be asked at enrollment, 14 and 30 days post enrollment.

10.4.14 Healthcare Visits Logistics

The Healthcare Visit Logistics form asks cost data at 30 days post study enrollment as well as barriers to care.

10.4.15 ED Visits and Hospitalizations

The ED Visits and Hospitalization form collects information about the index ED visit and any visits or hospitalization between the index and 30-day follow-up. Data is acquired for this form by patient report, EHR query and records matching (if patient consents to such matching).

10.5 Outcome Data

10.5.1 Engagement in Treatment Survey (Primary Outcome)

At 14 and 30 days post enrollment, participants will be asked to report AUD treatment received on their 7th and 30th day post enrollment target date (Day 30, with the ED enrollment visit being Day 0). The services reported by the patient will be confirmed with the addiction treatment provider. The Engagement in Treatment-Facility survey includes the type of treatment the participant is receiving (MAT, intensive therapy, detoxification, residential or inpatient treatment). Date of admission is recorded as well as the level of treatment received according to ASAM Levels of care, such as Level 1: Outpatient Treatment; Level II: Intensive outpatient treatment (including partial hospitalization); Level II: Residential/Inpatient Treatment; Level IV: Medically managed intensive treatment.

10.5.2 Process Outcome

The process outcome will be assessed using standardized Epic reports and billing data that are currently received as a standard part of monthly quality improvement. The process data elements include the monthly aggregate number of:

1) ED visits for patients with an ICD10 discharge or admission diagnostic code related to alcohol abuse
2) ED visits for patients with an ICD10 code related to alcohol abuse who have a completed RN alcohol screen
3) Number of ED visits for patients with an ICD10 code related to alcohol abuse who have a completed AUDIT-C
4) Number of ED visits for patients with an ICD10 code related to alcohol abuse who receive a referral for outpatient treatment

As noted these reports are currently used as part of MSBI EDs monthly QI data reporting. The reports are stripped of all identifiers and reported as aggregate numbers. These reports will be viewed monthly to assess compliance with quality metrics for patients with AUD.

11.0 FEASIBILITY COMPONENT

11.1 Study Procedures and Assessments

11.1.1 Rationale for study component

Initiation of patients with AUD onto MAT is common clinical practice but has typically been reserved for the out-patient setting. Unfortunately, many patients with AUD remain “hidden”, infrequently seeking care or interacting with out-patient healthcare resources. Not infrequently, however, these same individuals do seek care in the Emergency Department setting often as a result of circumstances related to their alcohol use. Expanding evidence based AUD treatment initiation options for these populations in the ED could have a major contribution to population health.

11.1.2 Overview of feasibility component

We will conduct a case series, n=20, of inductions of oral naltrexone in Emergency Department patients with moderate or severe alcohol use disorder. This study will be performed in a single ED by an investigator with extensive experience in ED initiated treatment with buprenorphine for patients with OUD and PrEP initiation for patient with activities that put them at high risk for acquiring HIV. Patients will be initiated on oral naltrexone and assessed for one hour post ingestion to monitor for any adverse medication effects. Daily craving and alcohol use will then be measured over 30 days as well as engagement in formal addiction treatment (primary outcome).

11.2 Primary Aim

The primary feasibility Aim 1 is to, over an 8-month period, identify 20 patients with moderate to severe AUD eligible and interested in immediate initiation of oral naltrexone. Consenting patients will be provided with immediate oral naltrexone initiation in the ED with a 14-day starter pack at the time of ED discharge. All participants will receive facilitated linkage to comprehensive out-patient care.

The primary outcome aim is to determine engagement in comprehensive addiction care at 14 and 30 days post enrollment.

11.2.1 Hypothesis

We can identify 20 ED patients interested in immediate initiation of oral naltrexone for AUD. We further hypothesize that a higher percentage of patients initiated on oral naltrexone in the ED will be engaged in comprehensive addiction care at 14 and 30 days post enrollment then patients who received SBIRT alone.

11.3 Secondary Aims

1) Medication adherence
2) Medication side-effects
3) Daily alcohol consumption
4) Desire to use – Craving Scale
5) Patient satisfaction
6) Health care utilization
7) Transition to long acting injectable naltrexone

11.4 Study Population

The study population, inclusion criteria, exclusion criteria, screening procedures, eligibility determination, informed consent procedures and compensation are identical to phase 1.

11.5 Study Procedures

Study procedures are identical to phase 1 with the following exceptions. In addition to all the measures and assessments detailed for phase 1, phase 2 study participants will also complete the following additional measures:

11.5.1 Pre Enrollment Assessments

No additional measures from phase 1.

11.5.2 Enrollment Assessments

No additional measures from phase 1.

11.5.3 Outcome Assessments

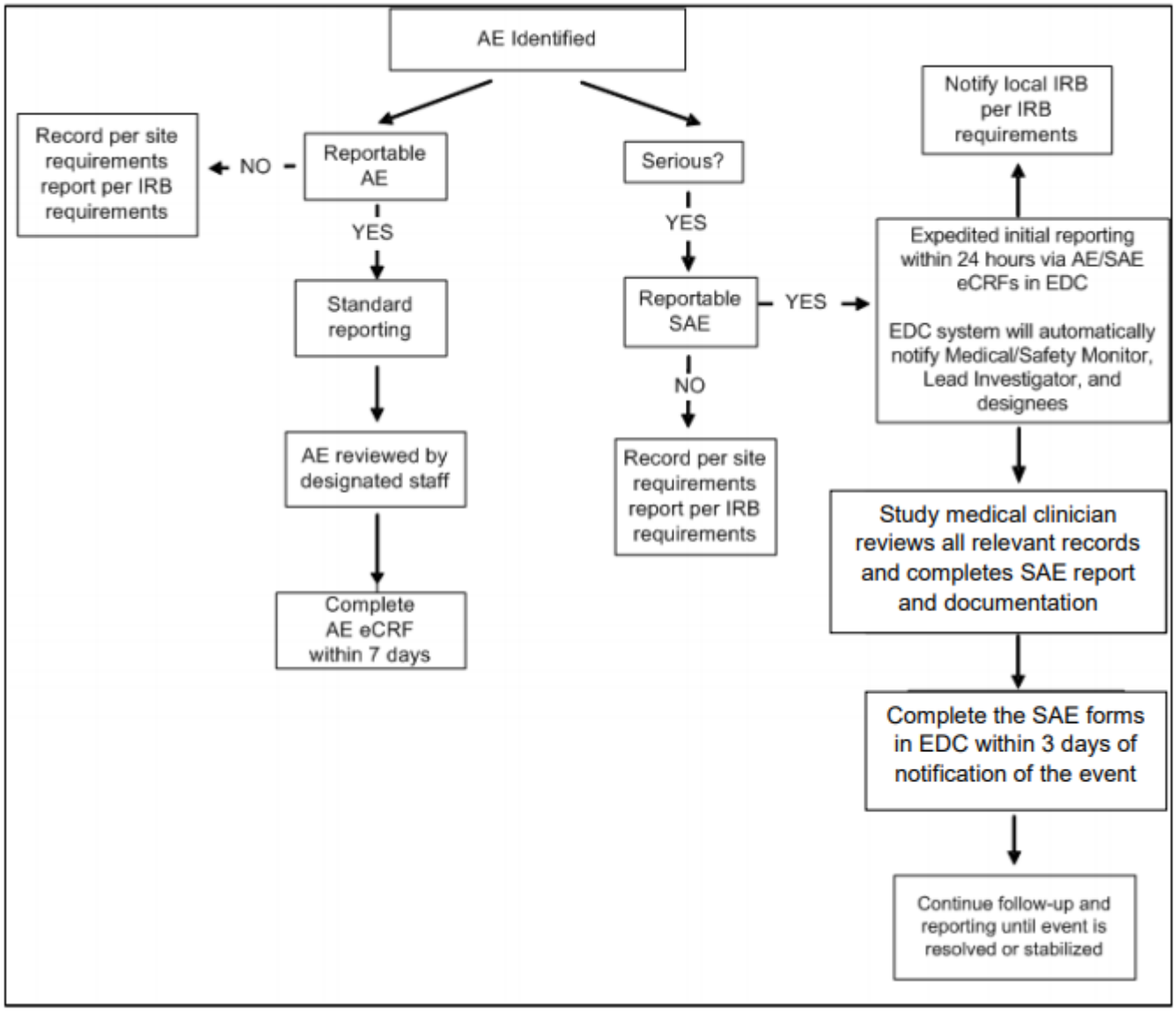
In addition to all the measures cited above for phase 1 we will also complete the following measures for phase 2 participants:

Medication adherence measures – Medication adherence will be measured by pill counts at 14 days post-enrollment. Patients having an in-person follow-up assessment at day 14 will be asked to bring their unused pills to their appointment. Patients having a remote follow-up at 14-days will be asked to show their pills to the RA if a visual platform is used or count the number of pills and report that to the RA. We will also use the single question GRIP measures (Appendix 26), a validated instrument to assess medication compliance.

Patient related inventory of side effects (PRISE) is a 7 item patient self-reported measure used to qualify side effects by identifying and evaluating the tolerability of each symptoms. Normally used for depression

related mediations but can be used to describe general side effects to any medication. This will be completed at the 14 day assessment only as that is the duration of the naloxone starter pack.

Adverse Events (AEs) and Serious Adverse Events (SAEs) – Adverse events will be captured and reported through the Adverse Event (AE) reporting mechanism described in Section 14 Given the small sample size and the fact that the medication being used is standard practice AEs and SAEs are expected to be low.



Protocol Deviation Form (Appendix 27) – This form will be used to capture protocol deviations, should they occur. The form will document a description of the deviation, how it occurred, the corrective action taken to resolve the specific deviation, as well as a description of the plan implemented to prevent further occurrences of similar deviations.

11.6 Intervention

Enrolled participants will all receive the same SBIRT intervention delivered to patients in phase 1. Participants in phase two will receive their first dose of oral naltrexone (50mg) while in the ED once their

liver function tests are completed and within the acceptable range (less than 3X upper limit of normal). Participants will be observed for 1 hour after medication administration to monitor for any side-effects.

11.7 Medication Packaging / Handling / Storage / Accountability

Oral naltrexone will be provided by the research pharmacy.

11.7.1 Study Medication Management

Research staff will be responsible for monitoring the medication supply to ensure that adequate unexpired medications are available for the study.

11.7.2 Dispensing Study Medication

All study medications will be prepared by the research pharmacy and dispensed by a pharmacist or licensed medical practitioner appropriately trained and authorized to dispense study medications per local regulations.

11.7.3 Study Medication Storage

Study medications will be stored in compliance with federal, state, and local laws and institutional policies. Study medications will be stored in a secured location under the conditions specified by the research pharmacy.

12.0 DATA MANAGEMENT AND STATISTICAL ANALYSES

12.1 Statistical Analysis

12.1.1 General approach

Nominal and ordinal categorical variables will be summarized as frequencies and percentages. Continuous variables will be summarized with the following descriptive statistics: N, mean, standard deviation, median, minimum, maximum, interquartile range, and range.

No imputation of missing data will be performed for any of the analysis given the pilot nature of the study and small sample size.

12.1.2 Analysis of Primary and Secondary Outcomes

For this pilot study we are most interested in feasibility and engagement in comprehensive addiction care 14 and 30 days post enrollment. In statistical analyses, participants will be included to the date of their last active follow-up visit. The primary outcome, engagement in comprehensive addiction care, will be reported using descriptive statistics including which includes the number/percentage engaged in care at 14 and 30 days.

Secondary outcomes: Multiple secondary outcomes will be assessed at 14 and 30 post oral naltrexone initiation including daily alcohol consumption assessed using timeline follow-back methodology, medication adherence assessed by self-report and pill counts, hospital admissions and ED utilization and degree of daily alcohol craving assessed using a validated craving measure. Adherence will be calculated at pre-

specified study time points for each participant. No a-priori comparisons are planned given the small sample size and pilot nature of the study. Secondary outcomes will be summarized using descriptive data.

12.1.3 Sample Size

This pilot study is meant to demonstrate the feasibility of ED initiated MAT for AUD. Sample size is based on projected ability to recruit within the proposed timeframe. Pilot data will be used to determine recruitment and attrition rates, as well as means and standard deviations for key measures that will be needed to plan a definitive trial of ED-initiated oral naltrexone for patients with moderate to severe AUD.

12.2 Data Management

With the exception of patient reported daily data captured in Qualtrics, data will be entered directly into REDCAP. The data stored in REDCAP will be password protected and access will be restricted to study staff. Data from REDCAP will be exported to STATA for analysis. Data stored in REDCAP will include participants' first and last name and contact information, in order to conduct follow-up contacts. Identifiers such as date of birth and Medicaid identification number will also be stored in REDCAP. Each participant will be assigned a unique identification code in REDCAP, which will be used in lieu of first and last name for analysis in STATA.

Data for analysis and records matching will be stored separately in a secure folder on the Mount Sinai server accessible only to the Principal Investigator (PI). Analytic datasets will not include participants' first and last name, contact information, date of birth, or any other identifying information.

Data from daily Qualtics surveys will be downloaded and stored in a secured folder. Data will be matched back to the participant and entered into the corresponding REDCAP profile by a member of the research staff. Hard-copy consent forms will be scanned and stored electronically in REDCAP and in a secure folder on the Mount Sinai server. Paper copies of signed Informed Consent Forms will be stored in a locked file cabinet that will only be accessible to the PI and study staff.

The PI will review all original consent forms that have been scanned into REDCAP and place a copy in a secure folder on the Mount Sinai server. All study documents will be stored for a period of six years after the study as per IRB policy.

All program and study staff who work with human subjects and/or data will undergo training on confidentiality and data management protocols in order to ensure data is collected, stored, and analyzed in a confidential manner.

There is no planned data sharing.

13.0 REGULATORY COMPLIANCE, ETHICS, AND REPORTING

This trial will be conducted in according with the current version of the protocol, in full conformity with the ethical principles outlined in the Declaration of Helsinki, the Protection of Human Subjects described in the International Council for Harmonization Good Clinical Practice (GCP) Guidelines, applicable United States (US) Code of Federal Regulations (CFR) and all other applicable state, local and federal regulatory requirements. The Lead Investigator will assure that no deviations from, or changes to the protocol will take place without prior agreement from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard to the trial participants.

13.1 Institutional Review Board (IRB) and Regulations

Prior to initiating the study, the PI will obtain written approval from the Icahn Mount Sinai School of Medicine IRB. If changes to the study protocol become necessary, protocol amendments will be submitted in writing by the investigators for IRB approval prior to implementation. In addition, IRBs will approve all consent forms, recruitment materials, and any materials given to the participants, and any changes made to these documents throughout study implementation. Approval of both the protocol and the consent form must be obtained before any participant is consented. If changes to the consent form are needed, a decision will be made regarding whether previously consented participants need to be re-consented. IRB continuing review will be performed annually. Unanticipated problems involving risk to study participants will be promptly reported to and reviewed by the IRB of record, according to usual practices.

13.2 Subject Information and Informed Consent

A HIPAA waiver will be requested for track board screening (no patient interaction

An alteration of informed consent and waiver of written documentation will be requested for the screening questions (Health Quiz and DSM).

Patient found to be study eligible based on screening will be offered study participation and will be asked to sign full, written informed consent.

We believe the alteration and waiver of written documentation for screening is in accordance with applicable federal regulations.

- The screening questions involves no more than minimal risk to the subjects;
- The screening could not practicably be carried out without the requested waiver or alternation;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

The study does not preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective. It is in conformance with 42 CFR 2.52, which allows for research-related provisions with regard to the disclosure of substance use disorder patient identifying information in the absence of the informed consent process and HIPAA authorization.

The informed consent form is a means of providing information regarding the study to a prospective patient participant and allows for an informed decision about participation in the study. Given the well-established safety and efficacy or oral naltrexone for AUD, we do not view the proposed study as high risk. However, given that oral naltrexone is being initiated in a different setting than usual we have taken precautions to minimize the risk of any adverse events. This includes ensuring that all inclusion criteria have been satisfied and no exclusion criteria are present prior to giving the first dose of oral naltrexone. We have also build in a 1-hour post medication administration observation period to monitor for any adverse effects. While this observation is not deemed necessary in clinical practice we thought that participant safety would be increased by being observed in a monitored setting.

Once eligibility is determined, the RA, who is knowledgeable about the study, will explain the significant elements of the study to the potential participant. Included in the consent will be language allowing the RA to contact community-based providers and programs to determine the patient's engagement in formal addiction treatment after trial enrollment. If the patient chooses to sign consent for study participation a copy of the consent will be provided to the participant. All persons obtaining consent will have completed

appropriate training in human subjects research. The participant will be informed that their participation is voluntary, and they may withdraw from the study at any time, for any reason without penalty. Individuals who refuse to participate of who withdraw from the study will be treated without prejudice.

The informed consent form must be updated or revised whenever important new safety information is available, or whenever the protocol is amended in a way that may affect participants' participation in the study.

13.3 Confidentiality

As described in the section on data management all necessary precautions will be taken to guard against breaches of confidentiality. All program and study staff who work with human subjects and/or data will undergo training on confidentiality and data management protocols in order to ensure data is collected, stored, and analyzed in a confidential manner.

13.4 Privacy Protections

The protection of subjects' privacy is a primary concern. To insure that all staff members are aware of the sensitivity of data to be collected, all staff will receive confidentiality training. The training will outline strict confidentiality protocols and the penalties involved for breaching protocol. Each person must be continuously aware of the responsibility to safeguard the privacy of all the participating individuals. Names or any other information about Program or Program Evaluation participants should never be divulged. Staff are to refrain from discussion about participants which might be overheard by non-study staff.

Participants' names and contact information will be collected in order to conduct follow-up encounters as part of the study. Participants will also be asked to provide the names and contact information of friends and family members, as additional contacts, should research staff be unable to reach them for follow-up. Only individual names and their contact information that the program participants offer to share will be tracked, and consents will be signed allowing research staff to communicate with them.

For issues that participants may deem sensitive or private, program and evaluation staff will remind participants that their information will be kept confidential and that they may choose to skip any questions that they prefer not to answer, and suffer no consequences with regard to participation the study.

13.5 Data Safety Monitoring

There will be no external data and safety monitoring committee for this study. This study involves no clinical or psychological intervention and as such there are no anticipated adverse events expected as part of study participation. Study outcomes will be tracked and monitored by the PI.

13.6 Potential Risks

Risks to participants in this study are not expected to be greater than minimal. Both the SBIRT intervention used in phases 1 and 2 as well as oral naltrexone as MAT for AUD are proven effective clinical interventions to decrease alcohol use in patients with AUD. The only change from standard practice is the setting in which oral naltrexone is being initiated. We have been using SBIRT for patients with AUD for the last year so this is not a change from standard ED practice. However, in regard to oral naltrexone initiation, standard practice has been for ED patients to be referred to care for outpatient initiation of MAT for AUD. This study moves that initiation step into the ED. We do not believe this change of venue for oral naltrexone initiation increases the risk above what would normally be considered standard practice.

However, given that we are initiating medication as part of this study and that medication has the potential for side-effects, patients will be informed of such effects in the informed consent document.

Other risks include loss of confidentiality. Participants are asked questions about illicit drug use and overdose, which may present social, legal, or economic risk if divulged to outside parties. As a result, the study team will take great care to protect confidential information.

All study interactions will be done one-on-one by phone, or in private or semi-private locations. Follow-up evaluations will be conducted by phone whenever possible. Participants can opt out of answering any question at any time.

13.7 Potential Benefits

There are potential direct benefits to participants in both phase 1 and phase 2 of the study. In phase 1 participants may benefit from the SBIRT intervention and referral to out-patient addiction care. In phase 2, in addition to the potential direct benefits of the SBIRT intervention participants craving for alcohol use and daily alcohol consumption could decrease with the initiation of oral naltrexone.

13.8 Alternatives

The only alternative to study participation is not to participate. Patients presenting with AUD typically receive a referral for out-patient addiction services.

13.9 Inclusion of Women and Minorities

We aim to enroll a diverse study population. There are no plans to exclude any gender, racial and/or ethnic group from study participation.

13.10 Pregnant and Breastfeeding Women

Pregnant and breastfeeding women are excluded from study participation. Oral naltrexone is not recommended in pregnancy as there is limited date on fetal effects. There is also limited data on the effects of oral naltrexone on breastfeeding infants.

13.11 Records Retention

Research records for all study participants (case report forms, source documents, signed consent forms and regulatory files) are to be maintained for 6 years as per IRB policy.

13.12 Safety Monitoring

The PI will review and provide consultation for each Adverse Event (AE) and Serious Adverse Event (SAE) as needed. These reviews will include an assessment of the possible relatedness of the event to the study intervention or other study procedures.

13.13 Data and Safety Monitoring Board (DSMB)

Given that the interventions being used in this study are part of standard clinical practice and considered no greater than minimal risk no DSMB is being used. The PI will be responsible for monitoring the safety of study participants.

14.0 ADVERSE EVENT REPORTING AND PROCEDURES

14.1 Definition of Adverse Events and Serious Adverse Events

An **adverse event** (AE) is any untoward medical occurrence in humans, whether or not considered study medication related which occurs during the conduct of the clinical trial. Any change from baseline in clinical status, ECGs, lab results, x-rays, physical examination, etc., that is considered clinically significant by the PI are considered AEs.

Suspected adverse reaction is any adverse event for which there is a reasonable possibility that the study medication caused the adverse event. A reasonable possibility implies that there is evidence that the study medication caused the event.

Adverse reaction is any adverse event caused by the study medication.

An **adverse event, suspected adverse reaction,** or **adverse reaction** is considered "**serious**" if, in the view of the PI it:

1) Results in a death
2) Is life-threatening
3) Requires inpatient hospitalization or prolongation of existing hospitalization
4) Results in persistent or significant incapacity of substantial disruption of the ability to conduct normal life functions
5) Is an important medical event that may not result in one of the above outcomes, but may jeopardize the health of the study participant or require medical or surgical intervention to prevent one of the outcomes listed in the above definition of serious event.

14.2 Definition of Expectedness

Any adverse event is considered "unexpected" if it is not listed in the package insert or is not listed at the specificity or severity that has been observed.

14.3 Medical and Psychiatric History

A thorough review of the participant's medical and psychiatric history of any chronic, acute, or intermittent preexisting or current illness, diseases, symptoms, or laboratory signs should be undertaken to avoid reporting pre-existing conditions as new AEs and to assist in the assessment of worsening in intensity or severity of these conditions that would indicate an AE. Stable chronic conditions which are present prior to clinical trial entry and do not worsen are not considered AEs.

14.4 Adverse Event Reporting

Appropriately qualified and trained personnel will elicit participant reporting of AEs and SAEs (Appendix 28) at each study visit. Study personnel will obtain as much information as possible about the reported AE/SAE to complete the AE/SAE forms and will consult with the PI as necessary.

Standard reporting, within 7 days of the site becoming aware of the event, will be required for all AEs. Expedited reporting (within 24 hours of their occurrence and/or site's knowledge of the event) is required for reportable SAEs.

Reportable adverse events will be followed until resolution, stabilization or study end.

14.5 PIs Role in Assessing Severity and Causality of Adverse Events

The PI will conduct an initial assessment of the serious, severity and causality when eliciting participant reporting of adverse events.

14.6 Guidelines for Assessing Severity

The severity of an adverse event refers to the intensity of the event defined by CDISC SDTM Severity Intensity Scale for Adverse Event:

Grade 1	Mild	Transient or mild discomfort (typically <48 hours), no or minimal medical intervention/therapy required, hospitalization not necessary (non-prescription or single-use prescription therapy may be employed to relieve symptoms, e.g., aspirin for simple headache, acetaminophen for post-surgical pain)
Grade 2	Moderate	Mild to moderate limitation in activity, some assistance may be needed; no or minimal intervention/therapy required, hospitalization possible.
Grade 3	Severe	Marked limitation in activity, some assistance usually required; medical intervention/ therapy required, hospitalization possible.

14.7 Guidelines for Determining Causality

The PI will use the following question when assessing causality of an adverse event to study medication where an affirmative answer designates the event as a suspected adverse reaction:

Is there a reasonable possibility that the study medication caused the event?

14.8 Site's Role in Monitoring Adverse Events

Staff education, re-training, or appropriate corrective action plan will be implemented as needed in response to reported AEs and SAEs.

14.9 Participant Withdrawal

The PI will apply his/her judgement to determine whether or not an adverse event is of sufficient severity to require that the participant be withdrawn from further study medication. A participant may also voluntarily withdraw from treatment due to what he/she perceives as an intolerable adverse event or for any other reason. If voluntary withdrawal is requested, the participant will be asked to complete an end-of-study medication visit to return unused medication and document end-of-medication outcomes.

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APPENDIX

Appendix 1: Patient Eligibility Summary

Patient Eligibility Summary

Date:

In order to meet eligibility, ALL inclusion answers must be "Yes."

1. Is the participant 18 years of age or older?
2. Is the participant being treated in the ED during screening hours?
3. Does the participant have a moderate to severe AUD as determined by DSM-5 criteria?
4. Is the participant able to speak and understand English?
5. Is the participant medically stable for an interview as determined by their primary ED provider?
6. Is the participant willing and able to consent to study participation?
7. Does the participant have two points of contact available for follow up?

In order to meet eligibility, ALL exclusion answers must be "no."

1. Is the participant psychiatrically unstable as determined by their primary ED provider?
2. Has the participant had an opioid dependence in the past year?
3. Does the participant have a urine toxicology test that is positive for opioids?
4. Is there a current or anticipated need for opioid medications for pain?
5. Is there an anticipated surgical procedure within 14 days of ED visit?
6. Does the participant have cirrhosis either from their medical history or self-report?
7. Is the participant pregnant or breastfeeding?
8. Does the participant require inpatient admission for medical or psychiatric issues?
9. Is the participant receiving a sexual assault forensics exam (SAFE)?
10. Is the participant suspected of having COVID-19?
11. Is the participant actively suicidal or homicidal?
12. Was the participant previously enrolled in either the implementation or feasibility phase of the study?
13. Is the participant on parole, in police custody or incarcerated at the time of the initial ED visit?
14. Is the participant currently or any time within the last 14 days enrolled in a formal addiction treatment, including by court order?
15. In the investigators opinion, is the participant unable to comply with study directions and follow-up?
16. Is the patient being admitted for inpatient alcohol detox?

Eligibility for Enrollment

1. Is the participant eligible for the study?
2. Did the participant provide informed consent?
    a. If yes, date:
3. Did the participant sign the medical release form?
    a. If yes, date:

Comments:

Appendix 2: Locator Form

We are going to ask you now to give us your name, address and phone number, if you have one, and the names and addresses of at least 2 people who know you. We will use this information to contact you after you leave the emergency department. This information can only be seen by the study staff working on the PrEPPED study.

We will always try to reach you first by your preferred method of contact.
If you give us permission we will communicate with you via email or text
If we are not able to reach you directly, and you give us permission, we will contact the people who know you whose information you have given to us. We will contact them by telephone.
If you give us permission to contact someone other than you we will only tell those people to give you a message to call us.
You may refuse to answer any question on this form.

Remember that all of this information is confidential.

Entered by: _____

Date: _____/_____/20_____

1..... Name: _____ ____ _____
..... First MI
.....Last
..... Nick Name (s):
..... _____

2. Age: _____ ..... Date of Birth: _____/_____/_____

3. MRN:_____ .....

4. Where do you currently live?
Address_____
.....
_____Apt No.: _____
..... City
....._____State _____ Zip Code: _____

Type of dwelling: _____
Whose place is it? _____
..... Name
..... Relationship

5. Is this the best address where we can send you information?
Address..... _____
.....
_____Apt No.: _____
..... City
....._____State _____ Zip Code: _____

Yes ❑ (skip to Q6)
No ❑ (complete address below)

6. What is the best way we should contact you by? .....
..... ❑ Regular mail ❑ Email ❑
Phone ..... ❑ Text

7. Primary phone number: (_____)_____ ❑ Cell ❑ Work ❑ Home
Share phone? ❑ No .....→..... ❑ Yes With whom?
_____

If we leave a message for you, what can we say?OK to text? ❑ Yes ❑ No
Mount Sinai BI ❑ ..... Hospital ❑
..... Navigator ❑
Other: ❑ _____

OK to text primary number? ❑ Yes ❑ No

Alternative phone number: (_____)_____ ❑ Cell ❑ Work ❑ Home
If we leave a message for you, what can we say? .....
Mount Sinai BI ❑ ..... Hospital ❑
..... Navigator ❑
Other: ❑ _____

OK to text alternative number? ❑ Yes ❑ No

Email address: __
_____

12. Which of the above is the best way to reach you quickly, if necessary?
Specify: _____

13. May we contact you at work? ..... ❑ Yes ❑ No ❑ Not working

Name of employer: _____

Work Address: _____

City: _____ State: _____ Zip: _____

.....Phone: _____

.....Can we leave a message at this number? ❑ Yes ❑ No

.....If yes, what can we say?

..... Mount Sinai BI ❑ Hospital ❑

..... Navigator ❑

Other: ❑ _____

14. OK to text work number? ❑ Yes ❑ No

SECONDARY CONTACT INFORMATION: Parent, sister/brother, other relative, good friend, neighbor, case worker/social worker or counselor. If not in contact with the person within the last month, ask for another contact.

CONTACT #1

Name:..... _____

Address:_____

Phone: ..... (_____)_____

What is your relationship to this person?.....

.....

If we leave a message with them for you, what can we say?

Mount Sinai BI ❑ ..... Hospital ❑

..... Navigator ❑

Other: ❑ _____

CONTACT #2

Name:..... _____

Address:_____

Phone: ..... (_____)_____

What is your relationship to this person?.....

.....

If we leave a message with them for you, what can we say?

Mount Sinai BI ❑ ..... Hospital ❑

..... Navigator ❑

Other:❑ _____

Appendix 3: Stigma Scale (PDDS)

Stigma Scale

Perceived Devaluation/Discrimination Scale (PDDS)

Please answer the following questions as either "Strong Disagree," "Disagree," "Agree," or "Strongly Agree."

1. Most people believe that people who formerly had an alcohol problem cannot be trusted.
2. Most people would not want to marry someone who has had an alcohol problem.
3. Most people believe that a person who has been hospitalized for an alcohol problem is dangerous.
4. Most people will think less of a person who has been hospitalized for an alcohol problem.
5. Most people look down on people who have been hospitalized for an alcohol problem.
6. Most people think that patients with an alcohol problem are just as intelligent as the average person.
7. Most employers will not hire a person who has been hospitalized for an alcohol problem.
8. Many people are afraid of people who have been hospitalized for an alcohol problem.

Appendix 4: Crime and Justice Assessment

Crime and Criminal Justice Assessment

1. Have you been incarcerated in the past 12 months? ☐ Yes ☐ No
    a. If Yes, how many days?
2. Have you been incarcerated in the past 30 days?
    a. If Yes, how many days?

3. How many times in the past 14 days have you committed the following crimes?	# of Times	a. If greater than "0" were you charged for it?
Dealing Narcotics		☐ Yes ☐ No
Vandalism		☐ Yes ☐ No
Stolen property		☐ Yes ☐ No
Forgery/counterfeiting		☐ Yes ☐ No
Fraud		☐ Yes ☐ No
Larceny/theft		☐ Yes ☐ No
Household burglary		☐ Yes ☐ No
Robbery		☐ Yes ☐ No
Rape/sexual assault		☐ Yes ☐ No
Homicide		☐ Yes ☐ No
Aggravated assault		☐ Yes ☐ No
Motor vehicle theft		☐ Yes ☐ No
Arson		☐ Yes ☐ No
Embezzlement		☐ Yes ☐ No

4. How many days in the last 30 days have you been in contact (either initiated by you or by the legal system) with the court, criminal justice system, or probation/parole office?
    a. Court:

b. Criminal justice system:
c. Probation/parole officer:

Appendix 5: Daily Substance Use

Daily alcohol use

Have you used alcohol in the past 24 hours? ☐ Yes ☐ No

If "yes," continue to the following questions.

In the past 24 hours did you drink beer? ☐ Yes ☐ No

If "yes": A standard serving of beer is 12 ounces for a regular beer (about 5% alcohol). How many beers have you had in the past 24 hours?

In the past 24 hours did you drink wine? ☐ Yes ☐ No

If "yes:" A standard glass of wine is 5 ounces and there are 5 glasses in a bottle of wine. Howmany glasses of wine have you had in the past 24 hours?

In the past 24 hours did you drink liquor? ☐ Yes ☐ No

If "yes:" A standard serving of liquor is a 1.5 ounce shot. There are approximately 17 shots in a 750ml bottle of liquor (also called a "fifth.") How many shots of liquor have you had in the past 24 hours?

Appendix 6: Health Services Utilization Report

Health Services Utilization - Baseline

Inpatient

Now I would like to review in detail any facilities in which you have been hospitalized overnight for any reason (physical, emotional, or substance use) during the last 7 days. Please include residential detoxification facilities, but do not include sober houses or halfway house stays.

Were any inpatient services used in the last 7 days? ☐ Yes ☐ No

If "Yes", how many inpatient facilities were utilized in the last 7 days?

Answer the following questions for each facility that was utilized in the last 7 days.

1. What type of facility did you stay at?
    a. Medical hospital
    b. Psychiatric hospital
    c. Inpatient substance use treatment (residential)
    d. Skilled nursing/extended care facility
    e. Other inpatient facility:
2. Service type:
    a. Medical/surgical
    b. Psychiatric (non-substance use)
    c. Substance use
    d. Psychiatric and substance use
3. What was the reason for the hospitalization?
4. Number of nights stayed in this visit:
5. Number of admissions to this facility in the last 7 days:
6. Visit paid for by:
    a. Insurance
    b. Self-pay
    c. No-cost

Outpatient

Next, I want to ask you about any time(s) you were an outpatient during the last 7 days. Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), not including this ED enrollment visit, and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotion, or substance use) during the last 7 days.

Were any outpatient services used in the last 7 days? ☐ Yes ☐ No

If "Yes", how many outpatient facilities were utilized in the last 7 days?

Answer the following questions for each facility that was utilized in the last 7 days.

1. What type of facility did you go to?
    a. Hospital-based clinic
    b. Federally-qualified (community) health center
    c. Private doctor's office
    d. Emergency department
    e. Urgent care center/walk-in facility
    f. Other:
2. Service type:
    a. Medical/surgical
    b. Psychiatric (non-substance use)
    c. Substance use

    d. Psychiatric and substance use
3. Provider type:
    a. Doctor
    b. Nurse
    c. Nurse Practitioner
    d. Physician's Assistant (PA)
    e. Chiropractor
    f. Other:
    g. I don't know
4. Number of visits to this facility in the last 7 days?
5. Average minutes per visit:
6. Visit(s) paid for by:
    a. Insurance
    b. Self-pay
    c. No-cost
7. Medications received/amount in the past 7 days:
    a. Naltrexone ☐ Yes ☐ No
        i. Oral ☐ Yes ☐ No
            1. Milligrams prescribed per day:
            2. Number of days prescribed:
        ii. Injectable ☐ Yes ☐ No
            1. Injection date:
            2. Date of second injection:
            3. Milligrams prescribed per day:
        iii. Other: ☐ Yes ☐ No
    b. Other medication:

Health Services Utilization – Follow Up
Inpatient
Now I would like to review in detail any facilities in which you have been hospitalized overnight for any reason (physical, emotional, or substance use) during the last 14 days (or number of days since last follow up). Please include residential detoxification facilities, but do not include sober houses or halfway house stays.
Were any inpatient services used in the past 14 days? (Since your ED visit/since the last follow up call) ☐ Yes ☐ No
If "Yes", how many inpatient facilities were utilized in the last 7 days?
Answer the following questions for each facility that was utilized in the last 7 days?

1. What type of facility did you stay at?
    a. Medical hospital
    b. Psychiatric hospital
    c. Inpatient substance use treatment (residential)
    d. Skilled nursing/extended care facility
    e. Other inpatient facility:
2. Service type:
    a. Medical/surgical
    b. Psychiatric (non-substance use)
    c. Substance use

    d. Psychiatric and substance use
3. What was the reason for the hospitalization?
4. Number of nights stayed in this visit:
5. Number of admissions to this facility in the last 7 days:
   Note: if a patient was hospitalized continuously since ED visit there would have been no admissions in the 14/30 days since initial ED visit.
6. Visit paid for by:
    a. Insurance
    b. Self-pay
    c. No-cost

Outpatient

Next, I want to ask you about any time(s) you were an outpatient during the last 14 days (from your enrollment visit in the ED OR since the last follow up). Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), not including this ED enrollment visit, and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotion, or substance use) during the last 14 days.

Were any outpatient services used in the last 14 days? ☐ Yes ☐ No

If "Yes", how many outpatient facilities were utilized in the last 14 days?

Answer the following questions for each facility that was utilized in the last 14 days.

1. What type of facility did you go to?
    a. Hospital-based clinic
    b. Federally-qualified (community) health center
    c. Private doctor's office
    d. Emergency department
    e. Urgent care center/walk-in facility
    f. Other:
2. Service type:
    a. Medical/surgical
    b. Psychiatric (non-substance use)
    c. Substance use
    d. Psychiatric and substance use
3. Provider type:
    a. Doctor
    b. Nurse
    c. Nurse Practitioner
    d. Physician's Assistant (PA)
    e. Chiropractor
    f. Other:
    g. I don't know
4. Number of visits to this facility in the last 14 days?
5. Average minutes per visit:
6. Visit(s) paid for by:
    a. Insurance
    b. Self-pay
    c. No-cost
7. Medications received/amount in the past 7 days:

a. Naltrexone ☐ Yes ☐ No
    i. Oral ☐ Yes ☐ No
        1. Milligrams prescribed per day:
        2. Number of days prescribed:
    ii. Injectable ☐ Yes ☐ No
        1. Injection date:
        2. Date of second injection:
        3. Milligrams prescribed per day:
    iii. Other: ☐ Yes ☐ No
b. Other medication:

Appendix 7: Health Status Report

Health Status Report

1. Did you come to the Emergency Department today primarily to receive treatment for referral for your alcohol use? ☐ Yes ☐ No
2. Do you have a medical care provider whom you usually see? ☐ Yes ☐ No
3. Where do you usually or most often go for medical care?
    a. Hospital-based clinic
    b. Federally qualified (community) health center
    c. Private doctor's office
    d. Emergency department
    e. Urgent care center/walk in facility
    f. Other:
4. Do you know your HIV status? ☐ Yes ☐ No
    a. If "Yes," what is your HIV status?
        i. Negative
        ii. Positive
            1. Undetectable
            2. Detectable
5. Do you know your Hepatitis C status? ☐ Yes ☐ No
    a. If "Yes," what is your Hepatitis C status?
        i. Never been positive/antibody non-reactive
        ii. Viral load negative
        iii. Viral load positive

Pain Section
Please answer the following questions on a scale of 0 to 10.

6. What number best describes your pain on average in the past week?
    a. 0 = no pain, 10 = pain as bad as you can imagine
7. What number best describes how, during the past week, pain has interfered with your enjoyment of life?
    a. 0= pain has not interfered at all, 10=pain has interfered extremely
8. What number best describes how, during the past week, pain has interfered with your general activity?
    a. 0= pain has not interfered at all, 10=pain has interfered extremely
9. In your lifetime have you ever been related for any psychological or emotional problems in a hospital or inpatient setting? ☐ Yes ☐ No

10. In your lifetime, have you ever been treated for any psychological or emotional problems as an outpatient/private patient? ☐ Yes ☐ No
11. In the past 30 days, have you been treated for any psychotically or emotional problems with counseling or medication? ☐ Yes ☐ No
12. Over the last 2 weeks, how often have you been bothered by any of the following problems? Not at all, several days, more than half the days, or nearly every day.
    a. Little interest or pleasure in doing things
    b. Feeling down, depressed, or hopeless
    c. Trouble falling or staying asleep or sleeping too much
    d. Feeling tired or having little energy
    e. Poor appetite or overrating
    f. Feeling bad about yourself or that you are a failure or have let yourself or your family down
    g. Trouble concentrating on things, such as reading the newspaper or watching television
    h. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual
    i. Thoughts that you would be better off dead, or of hurting yourself in some way
13. How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
    a. Not difficult at all
    b. Somewhat difficult
    c. Very difficult
    d. Extremely difficult
14. Any comments:

Appendix 8: HIV Risk Behaviors

HIV Risk Behaviors/Perception of Risks Questionnaire - Baseline

READ **This survey is going to ask you sensitive questions about your drug use, and sexual and HIV risk behaviors. The information you provide is being used for research purposes only and will not be linked to your name. This information is strictly confidential. Please be as honest as possible. Thank you.**

Sexual Behaviors with Main Partner

READ: ***First, I want to ask you specific questions about your vaginal, oral, and/or anal (i.e., in the bum) sexual practices with a main or steady partner. This could be a husband/wife, boyfriend/girlfriend, lover, or your live-in partner.***

Q1. In the past 30 days, has there been one person who you consider to be your main sexual partner?

.....YES 1
NO .....0 (SKIP TO Q12)

.....DK/UNSURE 9

.....REFUSED 7

Q2. How long have you been together?

..... YEARS |__|__|
.....MONTHS |__|__|
..... WEEKS |__|__|

DK/UNSURE..... 99
REFUSED…… 97

Q3. Is this person a male or a female ?

.....Male 2
.....Female1
.....
.....DK/UNSURE 9
.....REFUSED 7

Q4. Has your main partner ever been tested for HIV?

YES..... 1
NO ..... 0 (SKIP TOQ5)

DK/UNSURE.....9
REFUSED.....7

Q4a. What were his/her test results?

Results Were Positive 1
Results Were Negative.....2
DK/UNSURE.....9

REFUSED.....7

Q5. How likely do you think it is that your main sexual partner is having sex with someone else? Would you say he definitely is, probably is, probably is not or definitely is not?

Definitely Is 1
Probably Is.....2
Probably Not 3
Definitely Not.....4

DK/UNSURE.....9
REFUSED.....7

[IF MSM, SKIP TO Q7]

Q6. How many <u>times</u> in the last 30 days did you have vaginal sex with your main sexual partner (meaning a penis was inserted into her/your vagina)?

.....# OF TIMES |__|__|__|

DK/UNSURE..... 999
REFUSED 997

Q6a. Of these ____ (TOTAL FROM Q7) times, how many times was a male or female condom used?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q7. How many <u>times</u> in the last 30 days did you have anal sex with your main sex partner (meaning a penis was inserted into your butt/bum/bottom?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q7a. Of these ____ (TOTAL FROM Q8) times, how many times was a condom (male or female condom used?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q8. During the past 30 days, did you use alcohol just before or during sex with your main sexual partner?

YES 1
NO .....0 (SKIP TO Q10)

DK/UNSURE.....9
REFUSED 7

Q9. Have you ever had sex to receive money, alcohol, drugs, or other things from your main partner?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

Q10. Have you ever given money, alcohol, drugs, or other things to your main partner for sex?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

Sexual Behaviors with Casual Partners

READ: ***Next I'm going to ask you about casual sex partners. These are sex partners who were not main, steady partners or sex trading partners, but may be casual friends, or one-night stands.***

Q11. In the past 30 days, did you have vaginal or anal sex with a casual partner?

YES.....1
NO..... 0 (SKIP TO Q17)
DK/UNSURE.....9
REFUSED.....7

Q12. How many different casual partners did you have in the past 30 days?

OF CASUAL PARTNERS ..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q13. The last time you had sex with a casual partner did you use a male or female condom?

YES.....1
NO 0
DK/UNSURE.....9
REFUSED.....7

Q14. How many <u>times</u> in the last 30 days did you have vaginal sex with a casual partner?

OF TIMES ..... |__|__|__| [IF "0" SKIP TO Q15]

DK/UNSURE 999
REFUSED 997

Q14a. Of these <u>times</u> that you had vaginal sex with a casual partner, how many times was a male or female condom used?

OF TIMES ..... |__|__|__|

DK/UNSURE 999
REFUSED 997

Q15. How many <u>times</u> in the last 30 days when you had sex with casual partners, did any of your partners put their penis into your anus?

OF TIMES ..... |__|__|__| [IF "0" SKIP TO Q16]

DK/UNSURE 999
REFUSED 997

Q15a. Of these <u>times</u> that you had anal sex with a casual partner, how many times was a male or female condom used?

OF TIMES ..... |__|__|__|
DK/UNSURE 999
REFUSED 997

Alcohol, Drug Use, and Sex

Q16. During the past 30 days, did you use alcohol just before or during sex with a casual partner?

YES 1
NO ..... 0 (SKIP TO Q18)

DK/UNSURE 9
REFUSED 7

Sexual Behaviors with Trading Partners

READ: ***Next I'm going to ask you about sex with a trading partner, not including your main partner or a main sexual partner, that might have given you money, drugs, clothes, food, transport, or a place to stay in exchange for sex.***

Q17. Have you ever traded sex for drugs, money, food, clothing, shelter, or any other goods?

.....YES 1
.....NO 0
.....DK/UNSURE 9
.....REFUSED 7

Q18. During sex with any partner over the past 30 days, did you experience any problems with condoms (i.e. breakage, slippage, removal, or only put on half way)?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

HIV Risk Behaviors/Perception of Risks Questionnaire – Follow Up

READ **This survey is going to ask you sensitive questions about your drug use, and sexual and HIV risk behaviors. The information you provide is being used for research purposes only and will not be linked to your name. This information is strictly confidential. Please be as honest as possible. Thank you.**

Sexual Behaviors with Main Partner

READ: ***First, I want to ask you specific questions about your vaginal, oral, and/or anal (i.e., in the bum) sexual practices with a main or steady partner. This could be a husband/wife, boyfriend/girlfriend, lover, or your live-in partner.***

Q1. In the past 14 days, has there been one person who you consider to be your main sexual partner?

.....YES1
NO .....0 (SKIP TO Q12)

.....DK/UNSURE 9
.....REFUSED 7

Q2. How long have you been together?

..... YEARS |__|__|
.....MONTHS |__|__|
..... WEEKS |__|__|

DK/UNSURE..... 99
REFUSED…… 97

Q3. Is this person a male or a female ?

.....Male 2
.....Female1
.....
.....DK/UNSURE 9
.....REFUSED 7

Q4. Has your main partner ever been tested for HIV?

YES..... 1
NO ..... 0 (SKIP TOQ5)

DK/UNSURE.....9
REFUSED.....7

Q4a. What were his/her test results?

Results Were Positive 1
Results Were Negative.....2
DK/UNSURE.....9

REFUSED.....7

Q5. How likely do you think it is that your main sexual partner is having sex with someone else? Would you say he definitely is, probably is, probably is not or definitely is not?

Definitely Is 1
Probably Is.....2
Probably Not 3
Definitely Not.....4

DK/UNSURE.....9
REFUSED.....7

[IF MSM, SKIP TO Q7]

Q6. How many <u>times</u> in the last 30 days did you have vaginal sex with your main sexual partner (meaning a penis was inserted into her/your vagina)?

.....# OF TIMES |__|__|__|

DK/UNSURE..... 999
REFUSED 997

Q6a. Of these ____ (TOTAL FROM Q7) times, how many times was a male or female condom used?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q7. How many <u>times</u> in the last 14 days did you have anal sex with your main sex partner (meaning a penis was inserted into your butt/bum/bottom?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q7a. Of these ____ (TOTAL FROM Q8) times, how many times was a condom (male or female condom used?

OF TIMES..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q8. During the past 14 days, did you use alcohol just before or during sex with your main sexual partner?

YES 1
NO .....0 (SKIP TO Q10)

DK/UNSURE.....9
REFUSED 7

Q9. Have you ever had sex to receive money, alcohol, drugs, or other things from your main partner?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

Q10. Have you ever given money, alcohol, drugs, or other things to your main partner for sex?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

Sexual Behaviors with Casual Partners

READ: ***Next I'm going to ask you about casual sex partners. These are sex partners who were not main, steady partners or sex trading partners, but may be casual friends, or one-night stands.***

Q11. In the past 14 days, did you have vaginal or anal sex with a casual partner?

YES.....1
NO..... 0 (SKIP TO Q17)
DK/UNSURE.....9
REFUSED.....7

Q12. How many different casual partners did you have in the past 14 days?

OF CASUAL PARTNERS ..... |__|__|__|

DK/UNSURE.....999
REFUSED 997

Q13. The last time you had sex with a casual partner did you use a male or female condom?

YES.....1
NO 0
DK/UNSURE.....9
REFUSED.....7

Q14. How many <u>times</u> in the last 14 days did you have vaginal sex with a casual partner?

OF TIMES ..... |__|__|__| [IF "0" SKIP TO Q15]

DK/UNSURE 999
REFUSED 997

Q14a. Of these <u>times</u> that you had vaginal sex with a casual partner, how many times was a male or female condom used?

OF TIMES ..... |__|__|__|

DK/UNSURE 999
REFUSED 997

Q15. How many <u>times</u> in the last 14 days when you had sex with casual partners, did any of your partners put their penis into your anus?

OF TIMES ..... |__|__|__| [IF "0" SKIP TO Q16]

DK/UNSURE 999
REFUSED 997

Q15a. Of these <u>times</u> that you had anal sex with a casual partner, how many times was a male or female condom used?

OF TIMES ..... |__|__|__|
DK/UNSURE 999
REFUSED 997

Alcohol, Drug Use, and Sex

Q16. During the past 14 days, did you use alcohol just before or during sex with a casual partner?

YES 1
NO ..... 0 (SKIP TO Q18)

DK/UNSURE 9
REFUSED 7

Sexual Behaviors with Trading Partners

READ: ***Next I'm going to ask you about sex with a trading partner, not including your main partner or a main sexual partner, that might have given you money, drugs, clothes, food, transport, or a place to stay in exchange for sex.***

Q17. Have you ever traded sex for drugs, money, food, clothing, shelter, or any other goods?

.....YES 1
.....NO 0
.....DK/UNSURE 9
.....REFUSED 7

Q18. During sex with any partner over the past 14 days, did you experience any problems with condoms (i.e. breakage, slippage, removal, or only put on half way)?

YES.....1
NO 0

DK/UNSURE.....9
REFUSED.....7

Appendix 9: PROMIS 29+2 Profile (PROPr)

Physical Function	**Unable to Do (1)**	**With much difficulty (2)**	**With some difficulty (3)**	**With a little difficulty (4)**	**Without any difficulty (5)**
Are you able to do chores such as vacuuming or yard work?					
Are you able to go up and down stairs at a normal pace?					
Are you able to go for a walk of at least 15 minutes?					
Are you able to run errands and shop?					
Anxiety **In the past 7 days…**	**Never (1)**	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**
I felt fearful					
I found it hard to focus on anything other than my anxiety					
My worries overwhelmed me					
I felt uneasy					
Depression **In the past 7 days…**	**Never (1)**	**Rarely (2)**	**Sometimes (3)**	**Often (4)**	**Always (5)**
I felt worthless					
I felt helpless					
I felt depressed					
I felt hopeless					
Fatigue **In the past 7 days…**	**Not at all (1)**	**A little bit (2)**	**Somewhat (3)**	**Quite a bit (4)**	**Very much (5)**

I feel fatigued										
I have trouble starting things because I am tired										
How run-down did you feel on average?										
How fatigued were you on average?										
Sleep Disturbance In the past 7 days…	**Very good (1)**		**Good (2)**		**Fair (3)**		**Poor (4)**		**Very poor (5)**	
My sleep quality was										
In the past 7 days…	**Not at all (1)**		**A little bit (2)**		**Somewhat (3)**		**Quite a bit (4)**		**Very much (5)**	
My sleep was refreshing										
I had a problem with my sleep										
I had difficulty falling asleep										
Ability to Participate in Social Roles and Activities	**Never (1)**		**Rarely (2)**		**Sometimes (3)**		**Often (4)**		**Always (5)**	
I have trouble doing all of my regular leisure activities with others										
I have trouble doing all of the family activities that I want to do										
I have trouble doing all of my usual work (including work at home)										
I have trouble doing all the activities with friends that I want to do										
Pain Interference In the past 7 days…	**Not at all (1)**		**A little bit (2)**		**Somewhat (3)**		**Quite a bit (4)**		**Very much (5)**	
How much did pain interfere with your day to day activities?										
How much did pain interfere with work around the home?										
How much did pain interfere with your ability to participate in social activities?										
How much did pain interfere with your household chores?										
Cognitive Function Abilities In the past 7 days…	**Not at all (1)**		**A little bit (2)**		**Somewhat (3)**		**Quite a bit (4)**		**Very much (5)**	
I have been able to concentrate										
I have been able to remember to do things, like take medicine or buy something I needed										

Pain Interference In the past 7 days…	**0 (no pain)**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10 (worst pain imaginable)**
How would you rate your pain on average?											

Appendix 10: Patient Satisfaction and Attitudes Scale

Satisfaction and Acceptability Measures

Overall satisfaction with the screening procedures

How inconvenient did you find today's screening procedures?

Not Inconvenient 0	1	2	3	4	5	Very Inconvenient 6	Prefer not to answer

How difficulty did you find today's screening procedures?

Not at all difficult 0	1	2	3	4	5	Very Difficult 6	Prefer not to answer

How satisfied were you with today's screening process?

Very dissatisfied 0	1	2	3	4	5	Very satisfied 6	Prefer not to answer

Attitudes toward future Naltrexone usage

What effect do you think being screened today in the Emergency Department will have on your future Naltrexone use?

Less likely to start Naltrexone 0	1	2	No effect on future Naltrexone use 3	4	5	More Likely to start Naltrexone 6	Prefer not to answer

Would you be interested in starting Naltrexone today if we were able to give you the medications in the Emergency Department?

Would not be interested in starting today 0	1	2	3	4	5	Would start medication today if available 6	Prefer not to answer

Appendix 11: Alcohol Craving Scale

Alcohol Craving Scale

During enrollment these questions apply to the last week that you drank any alcohol.

If this is a daily assessment or 14 and 30 day follow- up assessment, these questions apply to the time period between your last completed assessment and now.

1. How often have you thought about drinking or about how good a drink would make you feel during this period?
    a. Never, that is, 0 times during this period of time = 0
    b. Rarely, that is, 1 or time times during this period of time = 1
    c. Occasionally, that is, 3 to 4 times during this period of time = 2
    d. Sometimes, that is 5 to 10 times during this period or 1 to 2 times a day = 3
    e. Often, that is, 11 to 20 times during this period or 2 to 3 times a day = 4
    f. Most of the time, that is 20 to 40 during this period, or 3-6 times a day = 5
    g. Nearly all of the time, that is, more than 40 times during this period or more than 6 times a day = 6
2. At its most severe point, how strong was your craving during this period?
    a. None at all = 0
    b. Slight, that is a very mild urge = 1
    c. Mild urge = 2
    d. Moderate urge = 3
    e. Strong urge, but easily controlled = 4
    f. Strong urge and difficult to control = 5
    g. Strong urge and would have drunk alcohol if it were available = 6
3. How much time have you spent thinking about drinking or about how good a drink would make you feel during this period?
    a. None at all = 0
    b. Less than 20 minutes = 1
    c. 21-45 minutes = 2
    d. 46-90 minutes = 3
    e. 90 minutes-3 hours =4
    f. 3-6 hours = 5
    g. More than 6 hours = 6
4. How difficult would it have been to resist taking a drink during this period of time if you had known a bottle were in your house?
    a. Not difficult at all = 0
    b. Very mildly difficult = 1
    c. Mildly difficult = 2
    d. Moderately difficult = 3
    e. Very difficult = 4
    f. Extremely difficult = 5
    g. Would not be able to resist = 6
5. Keeping in mind your responses to the previous questions, please rate your **overall average** alcohol craving for the stated period of time?
    a. Never thought about drinking and never had the urge to drink = 0

b. Rarely thought about drinking and rarely had the urge to drink = 1
c. Occasionally thought about drinking and occasionally had the urge to drink = 2
d. Sometimes thought about drinking and sometimes had the urge to drink = 3
e. Often thought about drinking and often had the to urge to drink = 4
f. Thought about drinking most of the time and had the urge to drink most of the time = 5
g. Though about drinking nearly all the time and had the urge to drink nearly all of the time = 6

Appendix 12: Generalized Anxiety Disorder Screener (GAD-7)

Over the last two weeks, how often have you been bothered by the following problems? Answers are not at all (0), several days (1), more than half the days (2), or nearly every day (3).

1. Feeling nervous, anxious, or on edge
2. Not being able t ostop or control worrying
3. Worrying too much about different things
4. Trouble relaxing
5. Being so resteless that is hard to sit still
6. Beocming easily annoyed or irritable
7. Feeling afraid, as if something awful might happen

Scoring:
0-4: minimal anxiety
5-9: mild anxiety
10-14: moderate anxiety
15-21: severe anxiety

If you chose that any of the above are problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all, somewhat difficult, very difficult, extremely difficult

Appendix 13: ED Health Quiz (EHQ)

ED Health Quiz (EHQ)

1. Do you smoke cigarettes every day, some days, or not at all?
   Answers: Every day, Some days, Not at all
2. **Assigned male at birth**: In the past year have you had 5 or more drinks in one day?
   Assigned female at birth: In the past year have you had 4 or more drinks in one day?
   Answers: Yes, No
3. Are you in the ED today for treatment of an injury?
   Answers: Yes, No
4. In the past 30 days have you used any alcohol?
   Answers: Yes, No
5. How many drinks of alcohol did you have in the last 7 days?
   Answer: number of drinks in the last 7 days
6. When was the most recent day/date you used alcohol?
   Answer: date
7. How often did you use alcohol in the past 7 days?

Answer: start with today and go back 7 days and document how many drinks were had on each of those days

8. In the past 12 months, have you used any opioid for any reason? Opioids include prescription opioids like Oxycodone (OxyContin, Perococet) or Hydrocodone (Vicodin) as well as illicit opioids like heroin or fentanyl.

   Answers: Yes, No

   If "Yes", complete the DAST-10 for opioid use. If the participant scores anything above a 0 they are not eligible for the study.

Drug Abuse Screening Test, DAST-10		
These questions refer to drug use in the past 12 months. Please answer Yes or No.		
1. Have you used drugs other than those required for medical reasons?	YES	NO
2. Do you use more than one drug at a time?	YES	NO
3. Are you always able to stop using drugs when you want to?	YES	NO
4. Have you ever had blackouts or flashbacks as a result of drug use?	YES	NO
5. Do you ever feel bad or guilty about your drug use?	YES	NO
6. Does your spouse (or parents) ever complain about your involvement with drugs?	YES	NO
7. Have you neglected your family because of your use of drugs?	YES	NO
8. Have you engaged in illegal activities in order to obtain drugs?	YES	NO
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	YES	NO
10. Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)?	YES	NO
Scoring: Score 1 point for each question answered "Yes," except for question 3 for which a "No' receives 1 point.		

Interpretation of Score		
Score	**Degree of Problems Related to Drug Abuse**	**Suggested Action**
0	No problems reported	None at this time
1-2	Low level	Monitor, reassess at a later date
3-5	Moderate level	Further investigation
6-8	Substantial level	Intensive assessment
9-10	Severe level	Intensive assessment

Appendix 14: DSM-5 Alcohol Use Disorder

DSM-5 Alcohol Use Disorder

Date of assessment:

1. Have you used alcohol in the past 12 months? ☐ Yes ☐ No

In the past 12 months, have you:

2. Had times when you ended up drinking more, or longer, than you intended? ☐ Yes ☐ No
3. More than once wanted to cut down or stop drinking, or tried to, but couldn't? ☐ Yes ☐ No

4. Spent a great deal of time in activities necessary to get alcohol, drink alcohol, or recover from its effects? ☐ Yes ☐ No
5. Wanted a drink so badly you couldn't think of anything else? ☐ Yes ☐ No
6. Found that drinking – or being sick from drinking – often interfered with taking care of your home or family? Or caused job troubles or school troubles? ☐ Yes ☐ No
7. Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink? ☐ Yes ☐ No
8. Continued to drink even though it was causing trouble with your family or friends? ☐ Yes ☐ No
9. More than once gotten into situations while or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in a dangerous area, or having unsafe sex)? ☐ Yes ☐ No
10. Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout? ☐ Yes ☐ No
11. Had to drink more than you once did to get the effect you want? Or found that your usual number of drinks had much less effect than before? ☐ Yes ☐ No
12. Found that when the effects of alcohol were wearing off you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there? ☐ Yes ☐ No

To meet criteria for an alcohol use disorder (AUD), the participant must answer "Yes" to at least 2 of the symptoms above.

- Mild disorder: 2-3 symptoms
- Moderate: 4-5 symptoms
- Severe: 6 or more symptoms

Appendix 15: Patient Health Questionnaire (PHQ-9)

Over the last *2 weeks*, how often have you been bothered by any of the following problems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so figety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
	add columns	+	+	

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card). TOTAL:

10. If you checked off *any problems*, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all _____
- Somewhat difficult _____
- Very difficult _____
- Extremely difficult _____

Interpretation of Total Score

Total Score	Depression Severity
1-4	Minimal depression
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

Appendix 16: Healthix Authorization and Information Sheet

Mount Sinai Beth Israel Mount Sinai Brooklyn Healthix

530

MRN:
V: Sex: DOB:

HEALTH INFORMATION EXCHANGE (HIE) AND HEALTHIX CONSENT FORM

The Mount Sinai Health Information Exchange ("Mount Sinai HIE") and Healthix share information about people's health electronically and securely to improve the quality of health care services. This kind of sharing is called ehealth or health information technology ("Health IT"). To learn more about Health IT in New York State, read the brochure, "Better Information Means Better Care." You can ask your health care provider for it, or go to the website www.ehealth4ny.org.

In this Consent Form, you can choose whether to allow the health care providers listed on the Mount Sinai HIE website www.mountsinaiconnect.org ("HIE Participants") to obtain access to your medical records through a computer network operated by the Mount Sinai HIE. This can help collect the medical records you have in different places where you get health care, and make them available electronically to the providers treating you. The list of HIE Participants is updated regularly.

You may also use this Consent Form to decide whether or not to allow employees, agents or members of the medical staff of "The Mount Sinai Health System" (defined in MS HIE Fact Sheet) to see and obtain access to your electronic health records through Healthix, which is a Health Information Exchange, or Regional Health Information Organization (RHIO), a not-for-profit organization recognized by the State of New York. This can also help collect the medical records you have in different places where you get healthcare, and make them available electronically to the providers treating you. This consent gives your permission for any Mount Sinai program in which you are a patient to access your records from your other healthcare providers authorized to disclose information through Healthix. A complete list of current Healthix Information Sources is available from Healthix and can be obtained at any time by checking the Healthix website at http://www.healthix.org or by calling Healthix at 877-695-4749. Upon request, your provider will print this list for you from the Healthix website.

YOUR CHOICE TO GIVE OR TO DENY CONSENT MAY NOT BE THE BASIS FOR DENIAL OF HEALTH SERVICES OR HEALTH INSURANCE COVERAGE. PLEASE CAREFULLY READ THE INFORMATION ON THE ATTACHED FACT SHEET, WHICH IS PART OF THIS CONSENT FORM, BEFORE MAKING YOUR DECISION.

Your Consent Choices. You can fill out this form now or in the future. I can also change my decision at any time by completing a new form. You have the following choices below. Please check Box 1 or 2:

☐ **1. I GIVE CONSENT to ALL of the HIE Participants listed on the Mount Sinai HIE website to access ALL of** my electronic health information through the **Mount Sinai HIE** and **I GIVE CONSENT to ALL employees, agents and members of the medical staff of Mount Sinai to access ALL of** my electronic health information through **HEALTHIX** in connection with any of the permitted purposes described in the fact sheet, including providing me any health care services, including emergency care.

☐ **2. I DENY CONSENT to ALL of the HIE Participants listed on the Mount Sinai HIE website to access** my electronic health information through the **Mount Sinai HIE** or and **I DENY CONSENT to ALL employees, agents and members of the medical staff of Mount Sinai to access ANY of** my electronic health information through **HEALTHIX** for any purpose, *even in a medical emergency.*

NOTE: UNLESS YOU CHECK THE "I DENY CONSENT" BOX, New York State law allows health care providers treating you in an emergency to gain access to your medical records, including records that are available through the Mount Sinai HIE and Healthix. IF YOU DON'T MAKE A CHOICE, the records will not be shared except in an emergency as allowed by applicable law.

If I want to deny consent for all Provider Organizations and Health Plans participating in Healthix to access my electronic health information through Healthix, I may do so by visiting Healthix's website at www.healthix.org or calling Healthix at 877-695-4749.

My questions about this form have been answered and I have been provided a copy of this form.

PRINT NAME OF PATIENT PATIENT DATE OF BIRTH

SIGNATURE OF PATIENT OR PATIENT'S LEGAL REPRESENTATIVE DATE TIME

PRINT NAME OF LEGAL REPRESENTATIVE (IF APPLICABLE) RELATIONSHIP OF LEGAL REPRESENTATIVE TO PATIENT (IF APPLICABLE)

61539 (06/16)

Mount Sinai Beth Israel Mount Sinai Brooklyn

Mount Sinai HIE and Healthix Fact Sheet

Healthix

Details about patient information in the Mount Sinai HIE and Healthix and the consent process:

1. Definitions.

- "The Mount Sinai Health System" refers to Mount Sinai Doctors Faculty Practice, the Icahn School of Medicine at Mount Sinai, and the following 7 Member Hospitals:
  - Mount Sinai Beth Israel
  - Mount Sinai Beth Israel Brooklyn
  - The Mount Sinai Hospital
  - Mount Sinai Queens
  - Mount Sinai Roosevelt
  - Mount Sinai St. Luke's
  - New York Eye and Ear Infirmary of Mount Sinai

2. How Your Information Will be Used. Consistent with New York State and Federal law, your electronic health information may be used by the HIE and Healthix Participants to:

- Provide you with medical treatment and related services.
- Check whether you have health insurance and what it covers.
- Improve Payers and Insurers ability to meet quality and performance program requirements by having a more complete view of a patient's clinical information.
- Provide Care Management Activities. These include assisting you in obtaining appropriate medical care, improving the quality of healthcare services provided to you, coordinating the provision of multiple health care services provided to you, or supporting you in following a plan of medical care.
- Provide Quality Improvement Activities. These include evaluating and improving the quality of medical care (and related services) provided to you and all Mount Sinai patients and Healthix members and participating organizations.

NOTE: The choice you make in this Consent Form does NOT allow health insurers to have access to your information for the purpose of deciding whether to give you health insurance or pay your bills. You can make that choice in a separate Consent Form that health insurers must use.

3. **What Types of Information About You Are Included.** If you give consent, the HIE Participants may access ALL of your electronic health information available through the Mount Sinai HIE and all employees, agents and members of the medical staff of Mount Sinai may access ALL of your electronic health information available through Healthix. This includes information created before and after the date of this Consent Form. Your health records may include a history of illnesses or injuries you have had (like diabetes or a broken bone), test results (like X-rays or blood tests), and lists of medicines you have taken. This information may relate to sensitive health conditions, including but not limited to:

• Alcohol or drug use problems	• Mental health conditions
• Birth control and abortion (family planning)	• HIV/AIDS
• Genetic (inherited) diseases or tests	• Sexually transmitted diseases

4. **Where Health Information About You Comes From.** Information about you comes from places that have provided you with medical care or health insurance ("Information Sources"). These may include hospitals, physicians, pharmacies, clinical laboratories, health insurers, the Medicaid program, and other ehealth organizations that exchange health information electronically. A complete list of current HIE Information Sources is available from Mount Sinai or your HIE Participant health care provider, as applicable. You can obtain an updated list of Information Sources at any time by checking the Mount Sinai HIE website http://www.mountsinaiconnect.org. You can also contact the Mount Sinai HIE Privacy Officer by writing to: HIPAA Compliance Office, The Mount Sinai Medical Center, 1 Gustave L . Levy Place, Box 1016, New York, NY 10029 or calling: 212-241-4669. A complete list of current Healthix Information Sources is available from Healthix and can be obtained at any time by checking the Healthix website at http://www.healthix.org or by calling Healthix at 877-695-4749.

Appendix 17: ED Visit Review

ED Visit Review (EDR)

Date of ED visit:

1. How was this patient identified?
    a. Health Quiz by research staff
    b. Emergency Department (ED) staff referral based on clinical care
    c. Electronic Medical Record (EMR) Review
    d. Other:
2. What was the chief complaint as written in the EMR? ☐ Yes ☐ No
3. Did the patient come to the ED specifically for alcohol use treatment? ☐ Yes ☐ No
    a. If "yes," which of the following:
        i. Intoxication
        ii. Withdrawal
        iii. Detox Request
        iv. Other:
4. What was the discharge diagnosis?
5. What are the ICD 10 code(s) for the discharge diagnosis?
6. What was the date of discharge?
7. Were any of the following medications given in the ED, prescribed at discharge, and/or given a take home dose? (yes/no answers for each of these options)
    a. Opioids
    b. Benzodiazepines
    c. Naltrexone
    d. Naloxone
8. Did the patient receive a referral to AUD treatment? ☐ Yes ☐ No
    a. If yes, give site name:
9. Did the patient receive a psychiatric evaluation during the ED visit? ☐ Yes ☐ No
10. Comments:

Appendix 18: Treatment Facility Survey

Treatment Facility Survey (ETF)

Date of assessment:

1. What type of provider/program is this?
    a. Office based provider
    b. Substance use treatment program
    c. Inpatient facility
    d. Other:
2. Was this patient engaged in a program at your facility or being treated at your office for their alcohol use disorder?

If "Yes", please review and answer the following questions.

3. What was the date of their admission into your program, or if office-based, when did their care begin?
4. Indicate the type(s) of treatment they are receiving for their alcohol use disorder:
    a. Naltrexone treatment:
        i. Oral:
        ii. Injectable:

    b. Short-term detoxification
    c. Inpatient
    d. Other:
5. How would you categorize the level of treatment received by this patient?
    a. No care received
    b. Level 1: Outpatient treatment
    c. Level 2: Intensive outpatient treatment (including partial hospitalization)
    d. Level 3: Clinically managed residential/inpatient treatment
    e. Level 4: Medically managed intensive inpatient treatment
    f. Other:

Appendix 19: Release Authorization Form

Mount Sinai Beth Israel

AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION

(Use this authorization form to obtain medical information from a Healthcare Provider / Facility not affiliated with MSBI)

2011

Patient Name _____ Date of Birth _____ M.R. # _____

Street, Apt # _____ S.S. # _____

City, State, Zip Code _____ Telephone # _____

1. I hereby authorize _____ to release information from my medical record to
   (Name of Provider / Healthcare Facility)
2. Name **MOUNT SINAI BETH ISRAEL -** _____
   (Specify Department or Individual)

   Address _____

   City, State, Zip Code _____

   For the purpose of (please check one)

   ☐ Continued Treatment ☐ Legal Review ☐ Insurance purpose

   ☐ Personal review of information ☐ Other (please specify) _____
3. I limit the information to be released to the following items: (Please check specific items)

   ☐ Discharge Summary ☐ Consultation ☐ Diagnostic test (e.g. Lab, X-ray, Radiology)

   ☐ Operative Note ☐ Pathology (please specify) _____

   ☐ Emergency Department Record ☐ Other (please specify) _____

   ☐ Outpatient Record (please specify) _____

Covering records from on or about (Date) _____ to (Date) _____

CONFIDENTIAL INFORMATION

4. If the requested portion of the record contains information pertaining to mental health or drug or alcohol treatment or contains HIV related information, you must specifically authorize the release of such information by initialing one or both of the following:

   _____ I understand that if my record contains **information concerning mental health and/or drug and alcohol treatment,** such information will be released pursuant to this authorization.

   _____ I understand that if my record contains **confidential HIV related information**, such information will be released pursuant to this authorization form. Confidential HIV related information is any information indicating that a person had an HIV related test, or has HIV infection, HIV related illness or AIDS, or any information which could indicate that a person has been potentially exposed to HIV.
5. I know I do not have to allow release of HIV related information and that I can change my mind at any time before it is released. If I experience discrimination because of release of HIV confidential information, I can call the NYS Division of Human Rights at (212) 480-2493 and/or the NYC Commission of Human Rights at (212) 306-7450.
6. **This authorization will automatically expire within six months from the date of signature.** I understand that I have a right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the Medical Records Department at Mount Sinai Beth Israel. I understand that the revocation will not apply to information that has already been released in response to this authorization.
7. I also understand that I have the right to refuse to sign this authorization. Your health care, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. You also have a right to receive a copy of this form after you have signed it.
8. I also understand that in an effort to prevent unauthorized re-disclosure Mount Sinai Beth Israel attaches a notice when sending out records that states. "re-disclosure is prohibited". However, the potential for an unauthorized re-disclosure may not be protected by federal confidentiality rules.
9. I also understand that in order to process this request to reproduce medical record information on a timely basis, Mount Sinai Beth Israel, in which I am requesting information from, may utilize a photocopy service and my signature authorizes the release of information to such photocopy service for the purpose of satisfying this request.

_____ _____

(Signature & Print Name of Patient/Representative/ or Legal Guardian) (Date) (Time)

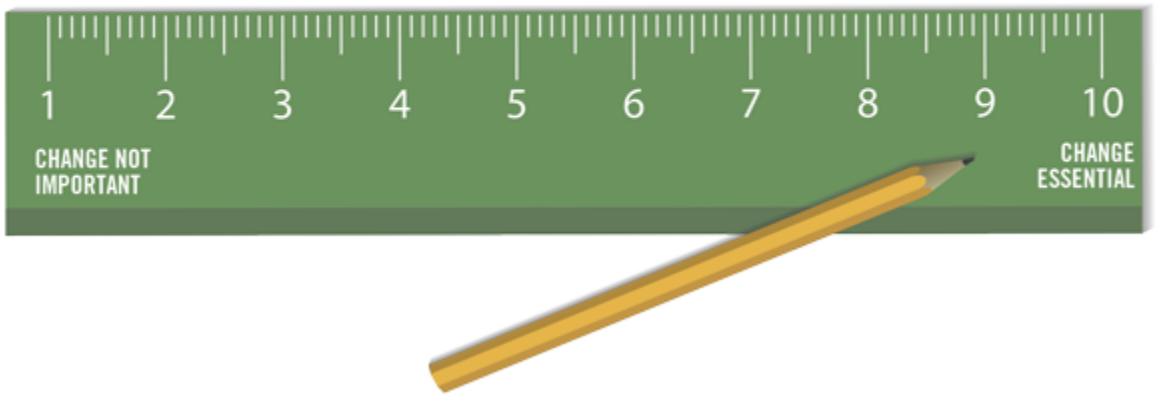
_____ _____

(If other than patient, relationship to patient) (Notary/Witness)

80939 (06/16)

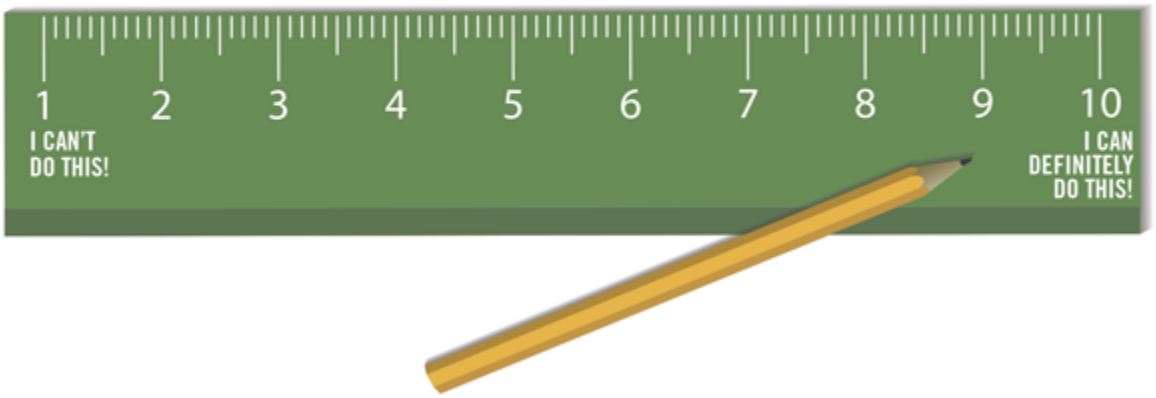
Appendix 20: Importance of Change Scale

First, ask a client on a scale of 1 to 10, 1 being not at all important and 10 being essential, how important is it to make a change. Alternatively, you could offer a piece of paper that looks like this and ask the client to mark the spot:



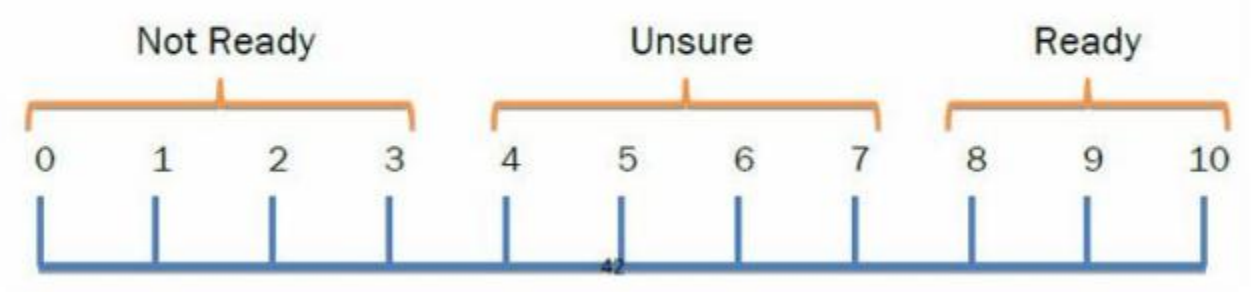
Appendix 21: Confidence Scale

"On that same 1 to 10 scale, how confident are you that you can make this change?"



Appendix 22: Readiness to Change Scale

On the following scale from 1 to 10, where 1 is definitely not ready to change and 10 is definitely ready to change, what number best reflects how ready you are to change _____ ?



Appendix 23: ASSIST-Lite

Alcohol, Smoking and Substance Involvement Screening Test

ASSIST-Lite

Instructions

The questions ask about psychoactive substance use in the PAST 3 MONTHS ONLY.

Ask about each substance in order and only proceed to the supplementary questions if the person has used that substance.

On completion of all the questions, count the number of "yes" responses to obtain a score for each substance, and mark the risk category.

Provide a brief intervention relevant to the risk category.

In the past 3 months	YES	NO
1. Did you smoke a cigarette containing tobacco?	☐	☐
1a. Did you usually smoke more than 10 cigarettes each day?	☐	☐
1b. Did you usually smoke within 30 minutes after waking?	☐	☐
Score for tobacco (count "yes" answers)	☐	
Risk category: ☐ Low (0) ☐ Moderate (1 or 2) ☐ High (3)		
2. Did you have a drink containing alcohol?	☐	☐
2a. On any occasion, did you drink more than 4 standard drinks of alcohol?	☐	☐
2b. Have you tried and failed to control, cut down or stop drinking?	☐	☐
2c. Has anyone expressed concern about your drinking?	☐	☐
Score for alcohol (count "yes" answers)	☐	
Risk category: ☐ Low (0 or 1) ☐ Moderate (2) ☐ High (3 or 4)		
3. Did you use cannabis?	☐	☐
3a. Have you had a strong desire or urge to use cannabis at least once a week or more often?	☐	☐
3b. Has anyone expressed concern about your use of cannabis?	☐	☐
Score for cannabis (count "yes" answers)	☐	
Risk category: ☐ Low (0) ☐ Moderate (1 or 2) ☐ High (3)		
4. Did you use an amphetamine-type stimulant, or cocaine, or a stimulant medication not as prescribed?	☐	☐
4a. Did you use a stimulant at least once each week or more often?	☐	☐
4b. Has anyone expressed concern about your use of a stimulant?	☐	☐
Score for stimulants (count "yes" answers)	☐	
Risk category: ☐ Low (0) ☐ Moderate (1 or 2) ☐ High (3)		
5. Did you use a sedative or sleeping medication not as prescribed?	☐	☐
5a. Have you had a strong desire or urge to use a sedative or sleeping medication at least once a week or more often?	☐	☐
5b. Has anyone expressed concern about your use of a sedative or sleeping medication?	☐	☐
Score for sedatives (count "yes" answers)	☐	
Risk category: ☐ Low (0) ☐ Moderate (1 or 2) ☐ High (3)		
6. Did you use a street opioid (e.g. heroin) or an opioid-containing medication not as prescribed?	☐	☐
6a. Have you tried and failed to control, cut down or stop using an opioid?	☐	☐
6b. Has anyone expressed concern about your use of an opioid?	☐	☐
Score for opioids (count "yes" answers)	☐	
Risk category: ☐ Low (0) ☐ Moderate (1 or 2) ☐ High (3)		
7. Did you use any other psychoactive substances?	☐	☐
If yes, what did you take?		
(Not scored, but prompts further assessment)		

Rapid guide to a Brief Intervention

Low risk: General health advice and encourage not to increase use.

Moderate risk: Provide a brief intervention using the FRAMES Model and offer take home information.

High risk: Provide a brief intervention using the FRAMES Model and encourage further assessment by a specialist drug and alcohol service. Facilitate referral and provide take home information.

Note: FRAMES - **F**eedback, **R**esponsibility, **A**dvice, **M**enu of options, **E**mpathy, **S**elf-efficacy.

Appendix 24: Cannabis Assessment

Cannabis Assessment

Instructions: When we use the term "marijuana/cannabis" we are referring to marijuana, cannabis concentrates, edibles, tinctures, and other inhaled or consumed products made with marijuana or cannabis. We are not referring to lotions, ointment, and CBD-only (e.g. hemp) products.

1. How often in the past 12 months have you used marijuana/cannabis?
    a. Never [If Q1=Never, end assessment]
    b. Less than monthly
    c. Monthly
    d. Weekly
    e. Daily or almost daily
2. When you used marijuana/cannabis during the past 12 mnoths, was it:
    a. For medical reasons
    b. For non-medical reasons
    c. For both medical and non-medical reasons
3. During the past 12 months, have you used marijuana/cannabis to help you manage any of the following: Check all that apply

a. Pain
b. Muscle spasm
c. Seizures
d. Nausea or vomiting
e. Sleep
f. Appetite
g. Worry or anxiety
h. Depression or sadness
i. Focus or concentration
j. Other symptoms (please specify):
k. None of the above

4. During the past 12 months, did you use marijuana/cannabis to replace, reduce, or stop use of alcohol? Yes/No
5. During the past 12 months, how did you use marijuana/cannabis? Please select all that apply.
    a. Smoked it (for example, in a joint, bong, blunt, spliff, or pipe)
    b. Vaporized it (for example, hash oil in an e-cigarette-like vaporizer, vape pen, or another vaporizing device)
    c. Ate it (for example, in brownies, cakes, cookies, or candy)
    d. Used it some other way (please list):

These next questions ask you to consider all the ways you typically use marijuana/cannabis:

6. How many days per week do you typically use any marijuana/cannabis?
    a. Less than 1
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. 6
    h. 7
7. On a typical day that you use marijuana/cannabis, how many times per day do you use it?
    a. Less than 1
    b. 1
    c. 2
    d. 3-4
    e. 5-9
    f. 10 or more
8. How do you feel your marijuana use affects your life?
    VAS

-100	0	+100
Definitely harmful	Neutral	Definitely beneficial

Appendix 25: HRQol

Health-Related Quality of Life (HRQol)

1. Would you say that in general your health is:

    a. Excellent
    b. Very good
    c. Good
    d. Fair
    e. Poor
    f. Don't know/Not sure
    g. Refused
2. Now think about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?
    a. Number of days:
    b. None
    c. Don't know/Not sure
    d. Refused
3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?
    a. Number of days:
    b. None (if both Q2 and Q3 are "None", skip next question)
    c. Don't know/Not sure
    d. Refused
4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?
    a. Number of days:
    b. None
    c. Don't know/not sure
    d. Refused

Activity Limitations Section

These next questions are about physical, mental, or emotional problems or limitations you may have in your daily life.

1. Are you LIMITED in any way in any activities because of any impairment or health problem?
    a. Yes
    b. No (Skip the rest of this section)
    c. Don't know/Not Sure (Skip the rest of this section)
    d. Refused (Skip the rest of this section)
2. What is the MAJOR impairment or health problem that limits your activities? Choose only one.
    a. Arthritis/rheumatism
    b. Back or neck problem
    c. Fractures, bone/joint injury
    d. Walking problem
    e. Lung/breathing problem
    f. Hearing problem
    g. Eye/vision problem
    h. Heart problem
    i. Stroke problem
    j. Hypertension/high blood pressure
    k. Diabetes

    l. Cancer
    m. Depression/anxiety/emotional problem
    n. Other impairment/problem
    o. Don't know/Not sure
    p. Refused
3. For HOW LONG have your activities been limited because of your major impairment or health problem?
    a. Days
    b. Weeks
    c. Months
    d. Year
    e. Don't know/Not sure
    f. Refused
4. Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house?
    a. Yes
    b. No
    c. Don't know/Not sure
    d. Refused
5. Because of any impairment or health problem, do you need the help of other persons in handing your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?
    a. Yes
    b. No
    c. Don't know/Not sure
    d. Refused

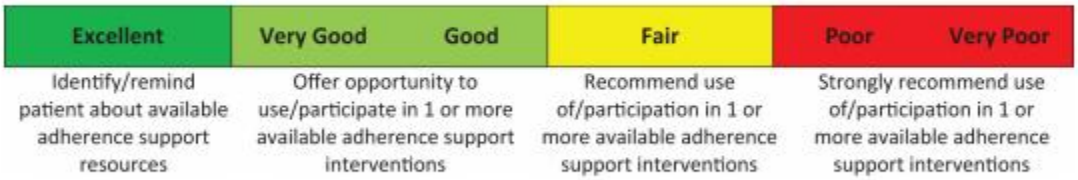
Healthy Days Symptoms Module

1. During the past 30 days, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation?
    a. Number of days:
    b. None
    c. Don't know/Not sure
    d. Refused
2. During the past 30 days, for about how many days have you felt SAD, BLUE, or DEPRESSED?
    a. Number of days
    b. None
    c. Don't know/Not sure
    d. Refused
3. During the past 30 days, for about how many days have you felt WORRIED, TENSE, or ANXIOUS?
    a. Number of days:
    b. None
    c. Don't know/Not sure
    d. Refused
4. During the past 30 days, for about how many days have you felt you did NOT get ENOUGH REST or SLEEP?

a. Number of days:
b. None
c. Don't know/Not sure
d. Refused

5. During the past 30 days, for about how many days have you felt VERY HEALTHY and FULL OF ENERGY?
    a. Number of days:
    b. None
    c. Don't know/Not sure
    d. Refused

Appendix 26: GRIP Adherence and Pill Counts Measure



Pill Counts Measure
How many naltrexone pills do you have left?

How was this reported to you?

1. RA counted in person
2. Participant reported via video conference and RA was able to visually see the pills
3. Participant reported via phone call

Appendix 27: Adverse Event Report (AD1) and Severe Adverse Event Report (AD2)

Adverse Event Report (AD1)
Adverse Event Onset Date:
Sequence number:

1. Adverse event name:
2. Date site became aware of the event:
3. Severity of event (pick one):
    a. Grade 1 – Mild
    b. Grade 2 – Moderate
    c. Grade 3 – Severe
4. Is there a reasonable possibility that study medication caused the event? ☐ Yes ☐ No
    a. If "Yes", action taken with study medication (select one):
        i. None

ii. Decreased drug
iii. Increased drug
iv. Temporarily stopped drug
v. Permanently stopped drug
vi. Participant terminated from study

5. If not caused by the study medication, alternative etiology (select one):
    a. None apparent
    b. Study disease
    c. Concomitant medication
    d. Other pre-existing disease or condition
    e. Accident, trauma, or external factors
    f. Concurrent illness/condition (not pre-existing)
    g. Study procedures
    h. Other:
6. Outcome of event (select one):
    a. Recovering/resolving (skip question 7)
    b. Recovered/resolved
    c. Recovered/resolved with sequelae
    d. Not recovered/not resolved (skip question 7)
    e. Fatal (skip question 7)
    f. Unknown (skip question 7)
7. Date of resolution or medically stable:

A response of "Yes" to any of the following will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.

8. Was this event associated with:
   If more than one option applies, select the most serious.
    a. Is the adverse event associated with a congenital anomaly or birth defect?
    b. Did the adverse event result in persistent or significant disability or incapacity?
    c. Did the adverse event result in death?
        i. If "Yes", date of death:
    d. Did the adverse event result in initial or prolonged hospitalization for the participant?
        i. If "Yes",
            1. Date of hospital admission:
            2. Date of hospital discharge:
    e. Is the adverse event life threatening?
    f. Is the adverse event an "Other serious" event (important medical event)?

Comments:
Study staff completing form:
Date completed:

Serious Adverse Event Summary (AD2)
Adverse event onset date:
Initial narrative description of serious adverse event:

1. Relevant past medical history: ☐ Yes ☐ No ☐ Unknown
   Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.
   Expand on relevant past medical history:

2. Medications at the time of event: ☐ Yes ☐ No ☐ Unknown
   Be sure to assess for dosage and date of last dose for the study medication, and any prior/concomitant medications as needed.

Medication (Generic Name)	**Indication**

3. Treatments for the event: ☐ Yes ☐ No ☐ Unknown

Treatment	**Indication**	**Date Treated (mm/dd/yyyy)**

4. Labs/tests performed in conjunction with this event: ☐ Yes ☐ No ☐ Unknown

Lab/Test	**Findings**	**Date of Test (mm/dd/yyyy)**

5. Follow-up:
   Include labs/test results as they became available, clinical changes, consultant diagnosis, etc.

Comments:
Study staff completing form:
Date completed:

Appendix 28: Protocol Deviation

Protocol Deviation (PD)
Date of Deviation:

1. Is this deviation related to one or more participants? ☐ Yes ☐ No
   a. If "Yes", how many participants?
   b. Please provide the associated participant IDs:
2. Date deviation identified:
3. Deviation type (select one):
   a. <u>Informed consent/assent procedure</u>
      i. No consent/assent obtained
      ii. Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
      iii. Other informed consent/assent procedures issues (specify):
   b. <u>Inclusion/exclusion criteria</u>

i. Ineligible participant randomized/inclusion/exclusion criteria not met or eligibility not fully assessed prior to randomization
ii. Other inclusion/exclusion criteria issues (specific):

c. Laboratory assessments
   i. Other laboratory assessment issues – minor (specify):
   ii. Other laboratory assessments issues – major (specify):

d. Study procedures/assessments
   i. Study assessment/procedures not followed in accordance with study protocol
   ii. Other study procedures/assessments issues (specific):

e. Adverse event
   i. AE not reported
   ii. SAE not reported
   iii. AE/SAE reported out of protocol specified timeframe
   iv. AE/SAE not elicited, observed, and/or documented per protocol
   v. Safety assessment not conducted per protocol
   vi. Other adverse events issues (specify):

f. Randomization procedures
   i. Stratification error
   ii. Other randomization procedures issues (specify):

g. Study medication management
   i. Medication not dispensed/administered in accordance with the study protocol
   ii. Other study medication management issues (specify):

h. Safety event
   i. Safety event assessment not conducted per protocol

i. Other significant deviations
   i. Destruction of study materials without prior authorization from sponsor
   ii. Breach of confidentiality
   iii. Other significant deviations issues – minor (specify):
   iv. Other significant deviations issues – major (specify):

4. Reason for the protocol deviation (selected all that apply):
   a. Research staff error
   b. Hospital error
   c. Laboratory error
   d. Pharmacy error
   e. Equipment/supply failure
   f. Issue with system down/glitch (e.g., EMR, REDCap)
   g. Participant unable to comply
   h. Participant refusal
   i. Investigator/study decision
   j. Other, specify:
5. Is this deviation related to COVID-19? ☐ Yes ☐ No
6. Brief description of what occurred:
7. Was/will there be corrective action for this event? ☐ Yes ☐ No
   a. If "No", describe why corrective action will not be taken:
   b. If "Yes", which of the following corrective actions were/will be taken (select all that apply):

i. Participant consent/re-consent was/will be obtained
ii. Research staff corrected/will correct error(s) and/or completed/will complete document(s)
iii. Participant corrected/will correct error(s) and/or completed/will complete document(s)
iv. Document(s) was/will be moved to correct file location(s)
v. Participant was/will be withdrawn from study
vi. Study drug administration was/will be halted
vii. Study assessment was/will be performed or repeated
viii. Other, specify:

c. As needed or requested, provide additional details about the corrective action plan:

8. Brief description of the plan to prevent recurrence (select all that apply):
    a. Complete local retraining (specify):
    b. Revise local SOP(s)
    c. Recalibrate/fix or replace faulty equipment/supplies
    d. Remove and/or replace incorrect/outdated document(s) from file(s)
    e. No site action needed
    f. Other (specify):
9. Is this deviation reportable to your IRB? ☐ Yes ☐ No
    a. If "Yes", will the IRB be notified at the time of continuing review? ☐ Yes ☐ No
        i. If "Yes", date of planned submission:
        ii. If "No", date of actual submission:

Comments:
Completed by:
Date completed:

Appendix 29: Contact Logs

Participant Contact Log

Contact visit: ☐ Day 14 ☐ Day 30
Please record all participant contact or contact attempts following enrollment.
Date:
Time:
Contact person: ☐ Participant ☐ Alternative Contact ☐ Other:
Contact type: ☐ Phone ☐ Email ☐ Mail
Result: ☐ Interview complete ☐ No answer ☐ Line busy ☐ Answering machine ☐ Subject Refusal ☐ Contact Refusal ☐ Unable to Contact ☐ Other:
Notes:
RA completing attempt:

Facility Contact Log

Date:
Time:
Contact person (Name and Phone number/email/address):
Contact type: ☐ Phone ☐ Email ☐ Mail
Result: ☐ Complete ☐ No answer ☐ Line busy ☐ Answering machine ☐ Refusal, needs follow up ☐ Medical records release not accepted ☐ Unable to Contact ☐ Other:
Notes:

RA completing attempt:

Appendix 30: Study Completion

Study Completion (STC)

Date completed:

Study staff completing form:

1. Did the participant complete the 30 day follow-up assessment visit? ☐ Yes (skip to question 2) ☐ No
    a. If "No," select the primary reason for study discontinuation?
        i. Participant deceased
        ii. Participant terminated for administrative issues
        iii. Participant was ineligible and should not have been enrolled in the study
        iv. Participant refused, non-specific
        v. Unable to contact participant
        vi. Participant terminated due to COVID-19
        vii. Participant terminated for other reason
            1. If "Participant terminated for administrative issues" or "Participant terminated for other reason", specify:
2. Date of last data collection with participant or date of withdrawn consent:
3. Comments:

Appendix 31: PRISE

5896525651

STAR*D PRISE

For office use only:

☐ Spanish ☐ By phone ☐ Ad hoc visit

☐ update

PRS

Level

Week in level

Patient ID

Date MM / DD / YYYY

Please indicate all symptoms you have experienced in the past week. These symptoms may or may not have been caused by your treatment.

1. GASTROINTESTINAL	4. NERVOUS SYSTEM
1.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Diarrhea ☐ Constipation ☐ Dry mouth ☐ Nausea/vomiting ☐ No symptoms in this category	4.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Headache ☐ Tremors ☐ Poor coordination ☐ Dizziness ☐ No symptoms in this category
1.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing	4.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing
2. HEART	**5. EYES/EARS**
2.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Palpitation (skipping a beat) ☐ Dizziness on standing ☐ Chest pain ☐ No symptoms in this category	5.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Blurred vision ☐ Ringing in ears ☐ No symptoms in this category
2.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing	5.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing
3. SKIN	**6. GENITAL/URINARY**
3.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Rash ☐ Increased perspiration ☐ Itching ☐ Dry skin ☐ No symptoms in this category	6.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause: ☐ Difficulty urinating ☐ Painful urination ☐ Frequent urination ☐ Menstrual irregularity ☐ No symptoms in this category
3.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing	6.2 If you had any symptoms over the last week, how bad was your WORST symptom? ☐ Tolerable ☐ Distressing

CRC ID

STAR D PRISE

☐ update PRS

Patient ID |_|_|_|_|_|_|_|_|_| Date |_|_|/|_|_|/|_|_|_|_| Level |_|_| Week in level |_|_|

7. SLEEP

7.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause:

- ☐ Difficulty sleeping
- ☐ Sleeping too much
- ☐ No symptoms in this category

7.2 If you had any symptoms over the last week, how bad was your WORST symptom?

- ☐ Tolerable
- ☐ Distressing

8. SEXUAL FUNCTIONING

8.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause:

- ☐ Loss of sexual desire
- ☐ Trouble achieving orgasm
- ☐ Trouble with erections
- ☐ No symptoms in this category

8.2 If you had any symptoms over the last week, how bad was your WORST symptom?

- ☐ Tolerable
- ☐ Distressing

9. OTHER

9.1 Check **ALL** symptoms that you have experienced during the past week regardless of cause:

- ☐ Anxiety
- ☐ Fatigue
- ☐ Poor concentration
- ☐ Decreased energy
- ☐ General malaise
- ☐ Other _____
- ☐ Restlessness
- ☐ No symptoms in this category

9.2 If you had any symptoms over the last week, how bad was your WORST symptom?

- ☐ Tolerable
- ☐ Distressing