Pre-Exposure Prophylaxis Provision in the Emergency Department (PrEPPED): A Pilot Feasibility Study
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Pre-Exposure Prophylaxis Provision in the Emergency Department (PrEPPED): A Pilot Feasibility Study

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1.0 LIST OF ABBREVIATIONS

Abbreviation	Definition
Ab	Antibody
eCRCL	Estimated creatinine clearance rate
ED	Emergency Department
FDA	Food and Drug Administration
FTC/TDF	Emtricitabine and tenofovir disoproxil fumarate
GRIP	Guidelines Regime Information Program
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HE	Health Educator
HIV	human immunodeficiency virus
iPrEP	Immediate PrEP initiation
PKC	Peter Kruger Clinic
PrEP	Pre-Exposure Prophylaxis
RCT	Randomized controlled trial
STI	Sexually Transmitted Infection
TAF/FTC	Emtricitabine and tenofovir alafenamide
VSQ-9	Visit specific satisfaction instrument

2.0 STUDY SYNOPSIS

This study will recruit and randomize 80 HIV Pre-Exposure Prophylaxis (PrEP) eligible Emergency Department (ED) patients to facilitated linkage to care for PrEP initiation versus immediate PrEP initiation in the ED (iPrEP) using a PrEP starter pack with facilitated linkage to care. The primary outcome is PrEP usage at 90 days post enrollment. Multiple secondary outcomes will also be measure including retention in care, STI diagnosis, risk behavior and PrEP adherence at 30, 60, and 90 days.

2.1 Study Design

Overview

1) Pre-Exposure Prophylaxis Provision in the Emergency Department (PrEPPED) RCT

We aim to assess the feasibility of initiating ED patients onto HIV PrEP. Specifically, among 80 PrEP eligible patients, this randomized controlled trial will compare the strategies of: a) ED screening with immediate PrEP (iPrEP) initiation, discharge with 14-day PrEP starter packs and facilitated linkage to outpatient care; vs. b) ED screening with facilitated linkage to an outpatient care for PrEP initiation. The primary outcome of interest is PrEP usage at 90 days with multiple exploratory secondary outcomes including PrEP adherence at 30, 60 and 90 days, retention in care, STI diagnosis, risk factor modification and program satisfaction. The intent of the proposed study is to provide data on recruitment and attrition rates, as well as means and standard deviations for key measures that will be needed to plan a definitive multicenter trial of ED-initiated PrEP.

3.0 INTRODUCTION

3.1 Background and Rationale

Despite an increasing armamentarium of behavioral and biomedical HIV prevention methods, since 2010 rates of new infection have remained around 40,000 annually.[1-6] The demonstrated efficacy and subsequent approval of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for pre-exposure prophylaxis (PrEP) for HIV by the FDA in 2012 was thought to represent a turning point that could significantly reduce the number of new infections.[7-10] Since approval, the promise of PrEP as a transformative intervention has yet to be realized. Despite the implementation of systems for clinical evaluation for and initiation of PrEP by primary care providers[11-14], HIV specialists[13, 15, 16], and STI clinics[14, 17-21], numerous barriers to PrEP expansion have been identified including: 1) patient and provider lack of knowledge[12, 13, 22-26], 2) lack of access to medical care among high-risk individuals[27], 3) provider discomfort and inexperience with screening for risk behaviors[13, 28, 29] and 4) insurance and affordability.[30, 31] This proposal seeks to expand access to and engagement in PrEP among high risk individuals though an innovative delivery approach in the non-traditional setting of the Emergency Department (ED) while addressing these four barriers enumerated above.
Traditionally, EDs have provided 'safety net' care for those who do not receive care elsewhere.[32-34] These "hidden populations" consist of individuals who are not engaged in primary care, are underserved, uninsured, and belong to minority groups.[34-36] It is these groups who are most at risk for acquiring HIV.[1, 37] Expanding the HIV prevention continuum in the ED to include PrEP assessment, initiation and linkage could have a major contribution to population level prevention.[31, 38-40] EDs already provide occupational and non-occupational post-exposure prophylaxis and thus have demonstrated operational capacity and experience with the risk factors, pathways and medications relevant to PrEP implementation.[41-43] For ED based PrEP to be broadly effective and implemented, however, it must be demonstrated that it is feasible in acceptable time frames. Experience with ED-based HIV testing interventions suggest this is likely; nonetheless data are needed.[44-51]

3.2 Innovation

roposal seeks to use the techniques of dissemination and implementation research to translate PrEP ning, initiation and linkage into an ED setting. Efficacy data strongly supports the value and safety of [52-55] Multiple demonstration projects have focused on implementing what was learned from clinical into practice settings to determine real-world effectiveness.[19, 56-63] The primary sites for these

demonstration projects have been STI, HIV clinics, and primary care. This proposal seeks to generate new insights and generalizable knowledge regarding intervention dissemination, implementation dissemination, implementation processes, facilitators, barriers and strategies for improvement for ED-initiated PrEP, a setting in which, PrEP delivery strategies can be disseminated to reach at-risk populations. Many of the proposed process and outcome measures fit within the RE-AIM model (Reach, Effectiveness, Adoption, Implementation, and Maintenance).[64] The three most applicable domains are reach, effectiveness and implementation and the RE-AIM checklist for those domains has been used to develop the research approach.[65] While the proposed implementation methodology has been used in other settings, the use of PrEP in the ED represents a novel approach to improve PrEP awareness and delivery.

The expansion of emergency medicine's (EM) mission beyond responding to emergencies into primary and secondary prevention has not been without controversy.[66, 67] Yet, lack of access to primary care and the urgent need to provide out-patient medication assisted treatment and other prevention services is forcing the mandate of the specialty to expand. Given that there is likely to be little change in healthcare structure to reverse this trend, EDs will continue to address primary and secondary prevention head-on. This proposal is another step toward pushing the specialty to expand its traditional role to include primary prevention for HIV. Trained health educators, embedded in the ED will be in an optimal position to target PrEP to at risk-individuals and have a real impact on primary prevention for HIV. This proposal is the first step toward demonstrating the effectiveness of an ED-based PrEP program to the profession at large.

3.3 Public Health Impact

Expanding access to Pre-Exposure Prophylaxis (PrEP) could have significant public health impact. It is estimated that even moderate increases in PrEP use could reduce new HIV infections by as much as 48,000 over the next five years. The goal of this project is to investigate the effect of an intervention to expand access by screening patients and initiating PrEP in the non-traditional setting of the Emergency Department.

4.0 SPECIFIC AIMS AND HYPOTHESIS:

Aim 1: Pre-Exposure Prophylaxis Provision in the ED (PrEPPED) Trial: The target is to identify 80 PrEP eligible patients over a 12 month period who are interested in initiating PrEP. These patients will randomized to either immediate PrEP (iPrEP) initiation in the ED, a 14-day PrEP starter pack at ED discharge and facilitated linkage to comprehensive outpatient care or facilitated linkage to care for PrEP initiation only.

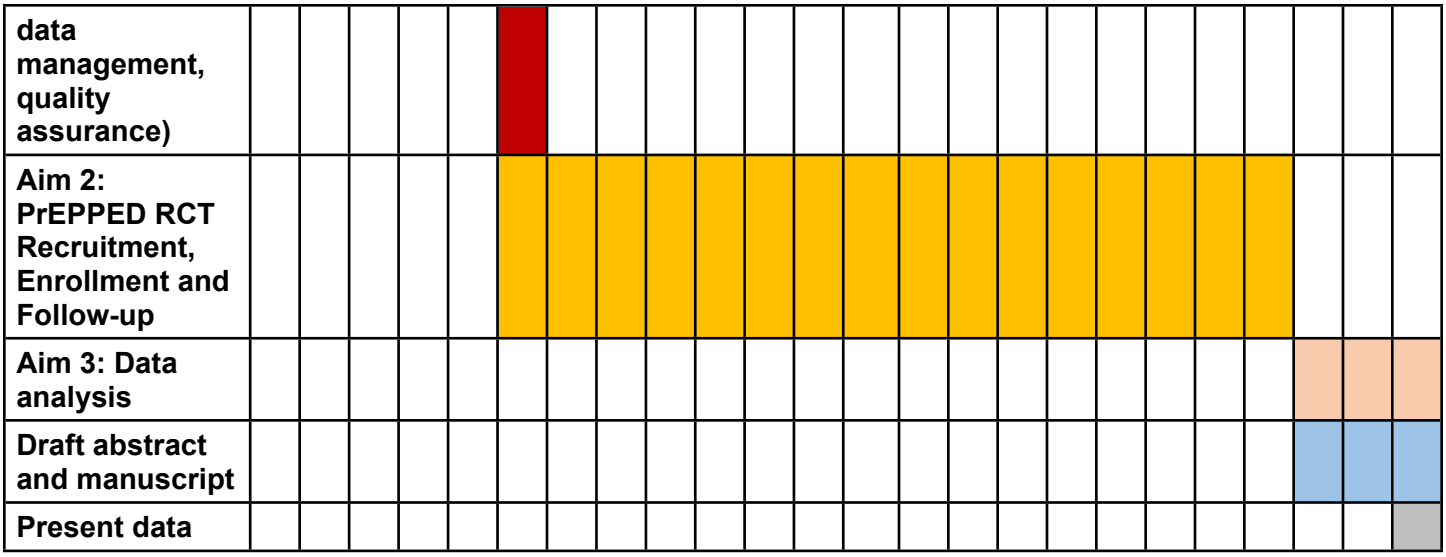
1a. Evaluate the impact of iPrEP and the PrEP "starter pack" on patients agreeing to PrEP initiation. The primary outcome is PrEP usage at 90-days post enrollment. Secondary outcomes include retention in care, STI diagnosis, risk behavior and PrEP adherence at 30, 60 and 90 days.

1b. 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 trial of ED-initiated PrEP.

5.0 STUDY DESIGN

5.1 Study Timeline

RCTTimeline																								
	Year 1												**Year 2**											
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
IRB Submission/Approval																								
Develop SOPs Aim 2: PPED RCT in, clinical, pharmacy,																								



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 as 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 Mount Sinai Hospital.

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 e or other governmental plans.

7.0 Randomized Controlled Trial

7.1 Primary Aim:

Among 80 PrEP eligible patients compare in a pilot 1:1 RCT design, the strategies of a) facilitated linkage for PrEP initiation within 14-days of ED visit and b) immediate PrEP (iPrEP) initiation in the ED, a 14-day PrEP starter pack at discharge and facilitated linkage.

The primary outcome is PrEP usage at 90 days post PrEP initiation visit. Secondary outcomes include retention in care, STI diagnosis, risk behavior and PrEP adherence at 30, 60, and 90 days.

7.2 Secondary/Exploratory Aims:

(1) Retention in care at 30 and 60 and 90 days post PrEP initiation
(2) PrEP usage at 30 and 60 days post PrEP initiation
(3) PrEP adherence at 30, 60, and 90 days post PrEP initiation
(4) Risk behavior at 30, 60, and 90 days post PrEP initiation
(5) STI diagnoses at 30, 60 and 90 day follow-up visits
(6) HIV infection
(7) Program satisfaction

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.[68] 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.[69] 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.[69] 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.[69]

8.2 Inclusion / Exclusion Criteria

INCLUSION CRITERIA
(1) Patients 13 years of age and above weighing at least 65 lbs., triaged to the adult or pediatric areas of the ED
(2) Medically stable as determined by their provider
(3) Able to speak English
(4) Willing and able to consent to study participation
(5) Patient is either treated and released or placed in extended observation
(6) Patient has at least two points of contact (can include phone, email, address, social media platform, etc.)

EXCLUSION CRITERIA
(1) Patient is younger than 13 years of age or weighing less than 65lbs.
(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
atient requires in-patient hospital stay
atient is receiving a sexual assault forensics exam (SAFE)
atient is suspected of having COVID-19
atient is suicidal, homicidal, or on security watch or in police custody

8.3 Number of Study Subjects

A single research assistant (RA), 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.

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 personnel will review the ED tracking board to identify patients with chief complaints that might indicate PrEP eligibility. This would include patients presenting to the ED for complaints related to sexually transmitted infections, non-occupational post-exposure prophylaxis (nPEP) or injection related complications. Study personnel will have to view the following identifiable information for recruitment screening purposes:

- 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. If the patient is an adolescent under the age of 18, the following additional recruitment steps will be taken. In addition to asking the provider for permission to speak with the patient the study staff will approach the patient and ask them if they are interested in participating in a study about sexual health. If the patient is interested, but is with their adult caretaker the study staff will politely ask as the patient and caretaker if the patient can complete the screening instrument in private. If the patient and caretaker agree the caretaker will be asked to leave the room at which point the study stuff will explain the study in more detail and ask the patient if they are willing to participate. If the patient would rather have the caretaker present for the screening and enrollment the study staff will ask to speak with the patient briefly in private to explain that the questions being asked are sensitive and include questions pertaining to sexual activity and drug use. If the patient still would like the caretaker present they will be invited back into the room. If the patient does not want the caretaker to be present they will be asked to wait outside the room until screening and enrollment are complete.

Study staff will approach the patient, introduce themselves, and ask for verbal consent to complete the behavioral screening questionnaire (ICAP screening instrument). If patients are eligible based on their behavioral screening they will be invited to participate in the RCT.

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 ssary informed consent requirements. Only IRB-approved Informed Consent documents and HIPAA sure allowing study access to protected health information in the patient's ED medical record will be

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.

Adolescents age 13-17 will also be informed that while parental consent is not required for study participation, follow-up clinical visits and PrEP medications will be billed to their insurance which will be visible to their caretakers or legal guardian. The additional risk of the parents becoming aware of the patient's PrEP use through insurance billing will be explained and noted in the informed consent document.

9.3 Study Procedures

After signing written informed consent study participants will undergo phlebotomy to assess the medical eligibility criteria for PrEP. This includes 1) Urine pregnancy for patients' assigned female at birth of child bearing age and capable of giving birth (2) 4th generation rapid HIV Ag/Ab test (3) Basic Metabolic Panel to obtain estimated creatinine clearance rate (eCrCl) (4) Hepatitis B Surface Antigen (HBsAg) (5) Hepatitis C antibody (HCV Ab) (6) Sexually Transmitted Infection (STI) testing when clinically indicated (Gonorrhea, Chlamydia and Syphilis). All patients will be assessed for symptoms of acute HIV infection. If these labs have already been performed for clinical purposes as part of the patient's Emergency Department clinical evaluation they do not need to be repeated.

After phlebotomy patients will complete the enrollment visit assessments as described below and be randomized to facilitated linkage to care for PrEP initiation versus immediate PrEP initiation in the ED (iPrEP) with a PrEP 14-day starter pack and facilitated linkage to care. Subjects started and discharged on PrEP from the ED will be provided with a medication guide that outlines how they should take their PrEP, common side-effects and reasons to call their doctor. This will same information will also be provided to them as part of the PrEP counselling session that they have with the health educator.

For patient randomized to iPrEP they will receive their first dose of oral PrEP in the ED. Patients' assigned male gender at birth (males and transgender females) will receive emtricitabine and tenofovir alafenamide. Patients' assigned female gender at birth (females and transgender males) will receive emtricitabine/tenofovir disoproxil fumarate. So long as patients do not have a known history of hepatitis B or renal disease, same day PrEP initiation, prior to confirmatory lab results, is safe and is supported by both NYC DOH guidelines and current literature.[70-72]

If patient's are found to have a clinical/laboratory contraindication for PrEP after ED discharge they will be informed of their ineligibility to continue PrEP by the PI and told to stop taking PrEP if they had already started (iPrEP group) or not start PrEP (standard referral group). Based on the implementation phase of the study we expect all laboratory results to be available within 48 hours of ED discharge.

Laboratory abnormalities will be addressed using standard ED clinical protocols. Patient with critical values will be asked to return to the ED for repeat evaluation and laboratory testing. Patients with abnormal values (HBV+ or elevated eCRCL) will be referred for out-patient evaluation. If a patient is found to have a clinical contraindication for PrEP their study participation will end.

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 1)
2) Satisfaction questionnaire and qualitative assessment (Appendix 2).
3) Attitudes towards PrEP Scale (Appendix 3)
4) CDC Sexual Behavior Questions (CSBQ) (Appendix 4)

to ED discharge all patients will receive a referral to an out-patient PrEP provider. Referrals are made gh the Institute of Advanced Medicine (IAM) PrEP Warm Line, the IAM REDCap referral system, or via at Prevention@montsinai.org. Patients will also be asked to sign an Authorization for Release of Medical

Information. The medical release form is needed to confirm clinic follow-up for patients not receiving their follow-up care within the Mount Sinai Health System.

Patients will be instructed at the time of discharge that they will be contacted by a member of the PrEP Warm Line to schedule follow-up with a PrEP provider. The decision to start PrEP for those not randomized to the iPrEP arm or to stop or continue PrEP for those randomized to the iPrEP arm will be a decision made by the patient in conjunction with their PrEP provider. The ED clinical team will be available to assist patients should have they have any concerns or problems before that linkage occurs. For those randomized to the iPrEP arm if they have any side-effects within the first 14-days of starter pack use they will contact the study team and a decision to continue or stop PrEP will be made after a discussion between the patient and the PI. All patients enrolled in the study will receive standard PrEP counseling which includes information about the need for frequent HIV testing and risk reduction strategies. The importance of follow-up with the PrEP provider will be stressed. We do not anticipate the need for any re-testing (HIV, LFTs, eCrCL) by the study team after ED discharge. These tests are not typically recommended until the patient has been on PrEP for at least 30 days and sometimes not until 90-days. All recommended follow-up testing will be the responsibility of the clinical PrEP provider.

9. 4 Randomization

Randomization will occur after the patient signs the informed consent document. The randomization sequence will be obtained by computer-generated random numbers and provided to research associates through a web portal.

9.5 Follow-up

All follow-up assessments will be performed over the phone. Follow-up assessments will occur at 30, 60, and 90 days post enrollment.

Follow-up assessments will include:

1) Attitudes toward Pre-Exposure Prophylaxis Scale (APS) (Appendix 3)
2) Section 4 of ICAP “Screening for Substantial Risk of HIV” (Appendix 5)
3) Satisfaction questionnaire and qualitative assessment and visit specific satisfaction instrument (VSQ-9) (Appendix 6)
4) Adherence information measured by (1) self-report. Self-report will be assessed with the single measure Guidelines Regimen Information Program (GRIP) guide and questions on last dose and number of missed doses since prior follow-up. (Appendix 7)
5) CDC Sexual Behavior Questions (CSBQ) (Appendix 4)
6) STAR*D PRISE (Side-effect assessment)

Assessment of engagement in PrEP care at 30, 60, and 90 days post enrollment will be verified by direct contact with the treatment provider/program provided or by EMR review if the patient is linked within the Mount Sinai Health System. If the patient is receiving their PrEP care outside of the Mount Sinai Health System, a signed release authorization form will be sent.

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 $25 gift card will be distributed in-person for completing the enrollment process at the initial ED visit and each follow-up assessment (30, 60, and 90 days).

participant completes the enrollment and all follow-up all daily assessments the total additional amount could receive would be $100.

9.7 Standard Intervention for all Participants: PrEP Counseling

All participants initiating PrEP will be provided with standard PrEP counseling by the Emergency Department Health Educator. PrEP counseling includes, (1) how PrEP works, (2) the benefits and risks of PrEP, (3) the need for adherence to the dosing schedule for PrEP to be protective and (4) how other safer sex and safer drug injection practices decrease the risk of acquiring drug-resistant HIV, other sexually transmitted infections (STIs), Hepatitis C virus, and pregnancy.

9.8 PrEP starter packs

14-day starter packs of FTC/TDF and FTC/TAF will be stored in the ED medication dispensing system. Standard operating procedures will be created for storage and dispensing. It should take no more than 5-minutes to retrieve the medication.

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.[73] 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 HIV risk and attitudes toward PrEP. The total expected time burden for the screening assessments is 30-60 minutes. Assessments collected at 30, 60, and 90 days post study enrollment will be similar.

10.3 Pre-Enrollment (Screening) Assessment Phase

10.3.1 ICAP PrEP Screening Questionnaire

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 PrEP behavioral eligibility criteria.

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

emographics forms collect information about demographic characteristics of the study participant, ing age, gender, cultural/ethnic group, education level, marital status, and type of insurance. This form is leted 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 90 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. Locator information will not be used in data analysis.

10.4.13 Satisfaction Scale

A short 3 question satisfaction scale will be used to measure satisfaction with the screening and linkage process. This will be asked at enrollment and the 30, 60, and 90-day follow-up assessments.

10.4.14 CDC Sexual Behavior Questions

A comprehensive sexual risk assessment for HIV and other STIs. This measure will be completed at enrollment.

10.4.16 Attitudes toward Pre-Exposure Prophylaxis Scale (APS)

A brief assessment of knowledge and attitudes regarding PrEP. This assessment will be completed at enrollment and each follow-up visit.

10.5 Follow-Up Assessments

10.5.1 Attitudes toward Pre-Exposure Prophylaxis Scale (APS)

A brief assessment of knowledge and attitudes regarding PrEP.

10.5.2 Section 4 of ICAP "Screening for Substantial Risk of HIV"

Section 4 focuses on screening for substantial HIV risk.

10.5.3 Satisfaction Scale

A short 3 question satisfaction scale will be used to measure satisfaction with the screening and linkage process. This will be asked at enrollment, 30, 60, and 90 days post enrollment.

10.5.4 Visit specific satisfaction questionnaire (VSQ-9)

The VSQ-9 is a visit-specific satisfaction instrument adapted by the American Medical Group Association from the Visit Rating Questionnaire.

10.5.6 Guidelines Regimen Information Program (GRIP) guide

The GRIP measure is a validated instrument to assess medication compliance. This will be asked at each follow-up visit.

10.5.7 STAR*D PRISE

The STAR*D PRISE measure is a validated instrument designed to measure side-effects of common antidepressant medications but has been used widely as a general measure of medication side-effects. This will be administered at each follow-up assessment for those patients taking PrEP.

10.5 Outcome Data

10.5.1 Engagement in Treatment Survey (Primary Outcome)

At 30, 60, and 90 days post enrollment, participants will be asked to report PrEP use and engagement in PrEP care. The services reported by the patient will be confirmed with the treatment provider or by review of the patient's medical record.

10.5.2 Treatment Facility Survey (Appendix 8)

The treatment facility survey will be completed to confirm where the patient is receiving PrEP follow up care. If they are outside of Mount Sinai Health System, they will be sent a signed authorized release form (Appendix 9).

11.0 DATA MANAGEMENT AND STATISTICAL ANALYSES

11.1 Statistical Analysis

11.1.1 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.

11.1.2 Analysis of Primary and Secondary Outcomes

Analysis will be on an intention-to-treat basis. In statistical analyses, participants will be included to the date of their last active follow-up visit. Comparisons between control and experimental (iPrEP) arms. To assess the success of randomization, a summary of the baseline variables by treatment group will be tabulated and univariate comparisons performed. The primary outcome, retention in care and PrEP usage, will be compared with proportions and Fisher's exact derived confidence intervals. Secondary outcomes: Secondary analysis will focus on determining how retention in care, risk behavior, adherence or STI diagnosis differ between the groups at any of the follow-up time points. PrEP adherence based on pill counts will be calculated by dividing the number of pills taken by the number of pills prescribed. Adherence will be calculated by study month for each participant. Group adherence comparisons will be compared using Wilcoxon rank sum test. Retention in care, STI diagnosis and risk behavior at each time point will be analyzed for each study visit. Retention in care and STI diagnosis will be treated as dichotomous variables for analysis. Measures of risk behavior will include consistency of condom use and number of sexual partners since prior study visit. Condom use will be treated as an ordinal variable and number of sexual partners as a continuous variable for analysis.

11.1.3 Sample Size

ilot RCT will be insufficiently powered to provide definitive efficacy data on retention and adherence for o study arms at 90 days. Yet, the pilot data is needed to determine recruitment and attrition rates, as well eans and standard deviations for key measures that will be needed to plan a definitive trial of ED-initiated

PrEP. For illustrative purposes we have included the following table of powers based on different retention in care rates in the control and experimental groups with the assumption that those retained in care will be using PrEP. This analysis assumes initial groups sizes of 40 and 40. The test statistic used is the two-sided Z test with pooled variance. The significance level of the test was targeted at 0.0500.

Power	**Control Group Retained in Care/PrEP**	**Experimental (iPrEP) Group Retained in Care/PrEP**	**Difference in Proportions**
0.0812	50%	55%	5%
0.1571	50%	60%	10%
0.2859	50%	65%	15%
0.4581	50%	70%	20%
0.6474	50%	75%	20%
0.8166	50%	80%	30%
0.9327	50%	85%	35%

The 50% follow-up rate for the control arm is based on and manuscript by Bogoch et als. entitled “Attrition Between the Emergency Department and Clinic Among Individuals Presenting for HIV Non-occupational Post exposure Prophylaxis published in *Clinical Infectious Diseases* in 2014.[74] The authors found that only 54% of patients seen in the ED for non-occupational post-exposure prophylaxis attended their first follow-up post-exposure clinic visit. This study did use appointment reminders but not the degree of facilitated linkage that will be used for the described ED PrEP program. In Project BRIEF, the HIV testing program described in the preliminary studies, the follow-up rate for newly infected HIV patients was 85%. Given that this will be the first effort at PrEP screening, initiation and linkage in the Emergency Department we do not expect to achieve the same degree of retention in care as we did for follow-up in Project BRIEF.

12.0 REGULATORY COMPLIANCE, ETHICS, AND REPORTING

12.1 Protection of Human Subjects

12.1.1 Risks to Human Subjects

The proposed project involves human subject’s research that is not exempt and involves a randomized clinical trial of a greater than minimal risk intervention to prevent HIV infection. Below we provide sufficient assurance to reviewers that the proposed research meets: (1) the requirements of the DHHS regulations to protect human subjects from research risks (45 CFR Part 46), (2) NIH policy requirements for Data and Safety Monitoring for Clinical Trials, (3) the ClinicalTrials.gov requirements, (4) the requirements of NIH policies on inclusion of women, minorities, and children and (5) the requirements of NIH policy on reporting race and ethnicity data for human subjects in clinical research.

12.1.2Human Subjects Involvement, Characteristics, and Design

Aim 1 includes examining the impact of iPrEP initiation in the ED by providing a 14-day PrEP “starter pack” and ating linkage with the primary outcome being PrEP usage at 90-days post index visit compared to the ate linkage only arm, as well as a number of exploratory secondary outcomes including PrEP initiation

and use at 30 and 60 days. We also 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 trial of ED-initiated PrEP.

For Aim 1, we will perform a randomized controlled clinical trial to compare the impact of immediate PrEP initiation (iPrEP) in the ED by providing a PrEP "starter pack" with facilitated linkage alone. The primary outcome is PrEP usage at 90-days post PrEP initiation visit. Participants will provide written informed consent for study participation. The consent to participate will also include 1) consent for investigators to collect prospectively collect clinical and sociodemographic data via medical record review and electronic data capture from the electronic health record. We anticipate 80 patients participating in the study associated with Aim 1.

Study procedures:

Aim 1: 80 PrEP eligible patients will be randomized 1:1 to either the experimental (iPrEP) arm or standard (out-patient PrEP) initiation arm. Patients in the iPrEP arm will receive a 14-day starter pack of PrEP and facilitated linkage. Patient in the control arm will receive facilitated linkage only. Patients in both arms will be followed for 90-days with telephone call follow-up visits scheduled for 30, 60 and 90 days post enrollment. Patients will be asked to complete satisfaction and medication adherence questionnaires at each scheduled follow-up

The setting of the human subjects' will be Mount Sinai Beth Israel Emergency Department.

Subject populations: The study population will include patients recruited in the Emergency Department at Mount Sinai Beth Israel Hospital

Mount Sinai Beth Israel Community Characteristics: The Mount Sinai Beth Israel (MSBI) ED draws patients form a large catchment area that in includes the Lower East Side, East Village, Two Bridges, Chinatown and Stuyvesant Town/Peter Cooper Village. The collective population of this geographic region is over 165,000. Included in this region are the following zip codes (10002, 10003, 10004, 10005, 10006, 10007, 10009, 10038). Within this geographic area are some of poorest residents in New York City. In one geographic region within this catchment area, median household incomes were 60% below the NYC mean based on year 2000 census data. Almost 35% of the population were foreign born with 65% of those emigrating from Asia, 26% emigrating from Latin America and 11% from Europe. The catchment area is also home to more than 15 shelters and supportive housing sites, among the highest concentration in NYC. While it is hard to provide exact numbers, there is a large proportion of homeless youth using these support services. It is estimated that 40% of these youth identify as LGBTQ and experience significant exposure to HIV. In regard to access to primary care services, 1 in 4 residents report not having a regular doctor, were currently uninsured, or went without health insurance at some time in the past year. The number of individuals previously tested for HIV is low with only about one fifth of Lower East Side residents having been tested for HIV in the past year. HIV risk factors are high with fewer than 4 in 10 (38%) adults who had more than 1 sex partner in the past year reported using a condom at their last sexual encounter.

Mount Sinai Beth Israel Emergency Department: 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.

12.2. Study Procedures, Materials, and Potential Risks

Aim 1

Study Procedures: Patients found to be eligible for PrEP will be randomized to immediate PrEP (iPrEP) initiation using a 14-day starter pack or PrEP initiation in the outpatient clinic. Both groups will have facilitated linkage to care. Follow-up study visits will occur at 30, 60 and 90days post PrEP initiation. The 30, 60 and 90 day assessments will over the phone.

Risks: Aim 1 involves randomization to one of two different PrEP initiation programs. PrEP initiation les risks that would be considered more than minimal. Patients in both groups will be prescribed citabine/tenofovir disoproxil fumarate (FTC/TDF) which will be used for women and transgender men or

emtricitabine/tenofovir alafenamide (FTC/TAF) which will be used for men and transgender women. Both of these medications are FDA approved and is being used for its intended purpose in the population for whom it is indicated. Known physical risks of emtricitabine/tenofovir disoproxil fumarate and emtricitabine/tenofovir alafenamide are impaired renal function, intolerable side effects including nausea, vomiting or diarrhea as well as hypersensitivity reaction and osteopenia with long term use. Patients will also be subject to the same psychological and privacy and confidentiality risks.

Sources of Data: Aim 1 data sources will come from the following

1) Socio-demographic questionnaires collected during screening and enrollment
2) Behavioral risk factor questionnaires collected at enrollment and 30, 60, and 90day follow-up
3) PrEP attitude and knowledge measures
4) Satisfaction questionnaires collected during enrollment and 30 , 60, and 90-day follow-up
5) Laboratory reports obtained from the patient's electronic medical record at enrollment and 30 and 90-day follow-up
6) Locator forms collected to obtain correct contact information collected at enrollment and 30 and 60 day follow up
7) VSQ-9 study visit questionnaires collected at 30 and 90-day follow-up
8) Adherence questionnaires collected at 30, 60, and 90-day follow-up
9) Facility follow-up questionnaire

Data for Aim 1 will be collected using a touch screen tablet and paper and pencil surveys administered by the RA. All data will be linked to the individual study participant but will be de-identified for analysis.

12.3. Adequacy of Protection against Risks

12.3.1 Recruitment & Informed Consent

Participants will be recruited from the MSBI Emergency Department during their ED visit. Participants will be recruited during a single 12-month period. The RA will screen all adult patients using the electronic medical record tracking board. The RA will obtain permission from the clinical team to approach the patient. Using a standardized script, the RA will give a brief description of the study and ask for consent to participate. Patients will be given a consent form that outlines the purpose of the study, length of time of the study, describe what is involved, their responsibilities if they take part in the research, information regarding compensation, potential benefits and foreseeable risks where applicable and study contact information. Potential participants will be asked if they would like time to think about the study and review the consent form. If requested, they will be given as much time as needed to review prior to signing the consent form. In addition to consenting to the survey, patients will also give consent to allow investigators to collect clinical and sociodemographic data from the medical record via chart review and electronic data capture.

The following additional steps will be taken for patient's age 13 to 18. In addition to asking the provider for permission to speak with the patient the study staff will approach the patient and ask them if they are interested in participating in a study about sexual health. If the patient is interested, but is with their adult caretaker the study staff will politely ask as the patient and caretaker if the patient can complete the screening instrument in private. If the patient and caretaker agree the caretaker will be asked to leave the room at which point the study stuff will explain the study in more detail and ask the patient if they are willing to participate. If the patient would rather have the caretaker present for the screening and enrollment the study staff will ask to speak with the patient briefly in private to explain that the questions being asked are sensitive and include questions pertaining to sexual activity and drug use. If the patient still would like the caretaker present they will be invited back into the room. If the patient does not want the caretaker to be present they will be asked to wait outside the room until screening and enrollment are complete.

12.4 Protections against Risk

nvestigators will make all efforts to minimize the physical, psychological, privacy and confidentiality risks man subjects.

Physical Risks: In regard to screening for study entry, patients' discovered to have a clinical/laboratory contraindication for PrEP will be informed and educated by the PI regarding the reason for their ineligibility. Clinical/laboratory abnormalities will be addressed using standard ED protocols. Patients with a primary care provider will be referred back to their doctor for further management. For patients without a primary care provider follow-up will depend on the specific exclusion criteria. Patients with decreased eCrCL will be referred to out-patient nephrology. Patients found to have HBsAg+ will be referred to out-patient Hepatology. Patients found to be HIV+ will be immediately linked to care at Peter Krueger Clinic as per standard ED protocols. Patients found to be pregnant will be referred to out-patient Obstetrics and Gynecology.

All patients initiated on PrEP in the ED will be monitored by the study team for the first 14-days (the duration of the starter pack) or until linked to their outpatient PrEP provider. While we will not be dictating out-patient clinical care we expect that patients will be managed as recommended in the US Public Health Service Pre-Exposure Prophylaxis Clinical Practice Guidelines. This includes repeat HIV testing every 3-months, repeat pregnancy testing for women who may become pregnant, STI testing for sexually active persons with signs or symptoms of infection and eCrCL monitoring (every 6-months).

Psychological Risks: Patients may suffer from anxiety and discomfort at any point during the study. This could be the result of learning that they have one of the medical exclusion criteria or PrEP initiation or a sexually transmitted infection. The RAs will undergo extensive training with the New York City Department of Health and Mental Hygiene (NYC DOHMH) to learn the appropriate counseling skills to address patients concerns. In the event that a RA needs additional assistance they will reach out to the Principle Investigator or social workers from the Emergency Department.

Privacy and Confidentiality Risks: The PI, the project manager (PM), and RAs will have access to identifiable study data. All hardcopy will be kept in a locked file cabinet in the PI's locked office. All study data will be entered into a password protected REDCap database or local databases behind the Mount Sinai firewall. The participant's anonymous study ID will be used on a linking sheet to connect survey data with medical chart review data. Otherwise, identifiable data will not be shared outside of Mount Sinai. All data shared outside of Mount Sinai (with biostatisticians) will be stripped of identifiers and transmitted via encrypted email message.

All possible steps will be taken to protect the participants against the unlikely and minimal risks described above. In order to ensure patient confidentiality, the following measures are proposed. Electronic data will be stored in password-encrypted files and transmitted by the research coordinator via secure, encrypted email to the PI. All paper data forms (used only when internet access is not available in the ED to permit data entry directly into REDCap), will be housed in a locked file cabinet within the PI's office until they are batched and brought in person to the RA for data entry. The RA will check the forms for completeness and enter all data into the REDCap database. The study database will be password-protected and encrypted and data files will be backed up routinely to guard against losses. Access to the study database will be limited to the study personnel.

All additional protections of participant confidentiality mandated by the Health Insurance Portability and Accountability Act (HIPAA) will be strictly followed. Additionally, the following data safeguarding procedures will be observed: 1) training staff on data sensitivity and data safeguards being employed to assure confidentiality, 2) storing and processing a hard copy in a centralized location, 3) securing a sensitive hard copy in a locked file, 4) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been computed, and 5) protecting the database by encrypted password. An encrypted master list of name to participant ID number will be kept by the PI separately in a locked location.

If at any time, a subject expresses verbal or nonverbal unwillingness to participate in any of the components of this proposal, the subject will be withdrawn from the study.

12.5. Vulnerable Subjects, if relevant to your study

duals who meet inclusion criteria may be asked to participate in research at times separate from clinical thus institutionalized individuals and prisoners will not be able to participate. Children less than age 13 (or but weighing less than 65lbs.) will be excluded from this research as these individuals are not eligible for

PrEP as it is currently approved by the FDA. It is anticipated that individuals from economically or educationally disadvantaged backgrounds will be enrolled, however special care will be taken to ensure that such individuals understand all aspects of the study and all of their rights as research participants. Urine tests will be conducted to ascertain the pregnancy status of participants and women found to be pregnant will not be able to continue in the study.

13.0. Potential Benefits of the Proposed Research to Research Participants and Others

Participants may directly benefit from the proposed research in several ways. Patients will be educated about PrEP and may discover they are eligible for PrEP based on ED screening. Initiating PrEP, either in the ED or in the out-patient clinic will reduce the likelihood of acquiring HIV. Patients randomized to the experimental arm will have a more rapid initiation of PrEP than those initiation PrEP in the out-patient clinic. If patients randomized to immediate PrEP initiation are adherent to the medication they may achieve earlier protection against HIV infection. If successful, the screening and initiation pathways created during this project could help reduce the HIV acquisition risk of future ED patients and have significant benefits to public health.

14.0. Importance of the Knowledge to be Gained

The proposed research could have a direct impact on future HIV prevention research. Ultimately, the studies proposed may result in improved knowledge on how expand access to PrEP. The proposed RCT will also provide the first data on the impact of ED initiated PrEP. The proposed work will form the foundation for a future multicenter RCT of ED initiated PrEP that could change ED based practice toward incorporating early portions of the PrEP cascade into routine ED based care for high risk individuals.

15.0. INCLUSION OF WOMEN, MINORITIES AND CHILDREN

15.1 Women and Minorities

Women and minorities will be included in the research without exception; no one will be excluded from participation based on sex/gender, race or ethnicity.

15.2. Children

Exclusion of groups: Children will be excluded from this research if they are age less than 13 or age 13-17 but weighing less than 65 lbs. as they are not eligible for PrEP.

16.0 Recruitment and Retention Plan

Participants will be recruited, enrolled and followed during one 12-month study period the MSBI emergency departments during their ED visit. The RA will screen all adult patients using the electronic medical record tracking board; to maximize the likelihood of identifying eligible patients, RAs will prioritize approaching patients with a chief complaint that that suggests PrEP eligibility (e.g. penile or vaginal discharge, drug overdose or withdrawal). A HIPAA waiver will be requested for these screening activities.

The RA will obtain permission from the clinical team to approach the patient. At this point, the research coordinator will approach the patient to provide information about the study, and if the potential participant is interested, verbal consent will be sought for PrEP behavioral eligibility screening. Patients that meet behavioral criteria for PrEP and are interested in participating will sign written informed consent will be obtained. Patients will be given a consent form that outlines the purpose of the study, length of time of the study, describe what is involved, their responsibilities if they take part in the research, information regarding compensation, potential benefits and foreseeable risks where applicable and study contact information. Potential participants will be asked if they would like time to think about the study and review the consent form. If requested, they will be given as much time as needed to review prior to signing the consent form. Participants will be informed of the

data sharing plan and the protections against identification of individuals associated with it. In addition to consenting to the survey, patients will also give consent to allow investigators to collect clinical and sociodemographic data from the medical record via chart review and electronic data capture.

To maximize retention we will use a Locator Form to collect the study participants current address, email address, phone numbers and, with consent, private social media information. In order to facilitate linkage and follow-up, we will also collect similar information for friends and family who know how to reach the patient. All follow-up assessments will be conducted at 30, 60, and 90 from PrEP initiation. All follow-up assessments will be conducted by telephone. Patients will be mailed an appointment reminder and receive a phone call a week and a day before their scheduled assessment. Patients who miss one or more than one follow-up assessment will continue in the study so long as it is within 90 days of their enrollment.

We will provide a $25 cash incentive for all participants to complete their enrollment, 30, 60 and 90-day follow-up assessments.

17.0 Data Safety Monitoring Plan

17.1 Roles and Responsibilities

To meet the study's ethical responsibility to its patients, results will be monitored during the trial by Dr. Cowan (PI). There will be no external data and safety monitoring committee for this study. Study outcomes will be tracked and monitored by the PI.

Study staff are required to disclose any financial conflict of interest to our institutional compliance office. Any identified conflicts of interest are indicated to the patient in the study consent form.

17.2 Trial Safety

Events that would preclude a participant from continuing the intervention:

Safety concerns: Guidelines published by the Centers for Disease Control and Prevention (CDC) provide clear guidance for clinicians prescribing emtricitabine/tenofovir disoproxil fumarate or emtricitabine/tenofovir alafenamide for pre-exposure prophylaxis (PrEP). Indications for not starting or stopping PrEP once started would include renal insufficiency (eCrCL of ≤60 ml/min), HIV infection, Hepatitis B, pregnancy, signs or symptoms of acute HIV infection, possible HIV exposure within the last 72 hours. Indications for stopping PrEP would be a new HIV or Hepatitis B infection, worsening renal function, intolerable side effects, hypersensitivity reaction, osteopenia or pregnancy. In the group of patients randomized to iPrEP if any these safety concerns arise during the 14 days the patient is taking the PrEP starter pack they will be addressed by the PI and the patient will be withdrawn from the study since they will no longer be considered PrEP eligible.

Participants could also be removed from the study by the investigator if they do not complete any follow-up assessments within 90-days of enrollment.

Managing any medication related issues: In the group of patients randomized to iPrEP medication related side-effects that occur while the patient is taking the 14-day starter pack will be addressed by the PI. After 14-days or linkage to care (whichever occurs first) the treating PrEP provider will manage the patient as clinically indicated. For any medication related emergency we will provide a “study card” with a number to call to speak with a physician and inform patients if they need immediate treatment to go to the closest emergency room. There is no wash-out period. Patients will told to inform their treating provider of any other medications they are taking including any over-the-counter medicines. For those patients who wish to discontinue PrEP, we will mend a test to determine HIV status at the time of discontinuation. We will also enquire about the reason EP discontinuation, recent medication adherence and reported sexual risk behavior.

Protection against risks: Participants will be told that their involvement is voluntary. All data obtained during this study will be kept strictly confidential. All hard copy information will be kept in a separate private research room, in a cabinet, under lock and key. A password protected and secured database will hold all computer data. Access to the data will only be open to the co-PIs, co-investigators, and the research associates. All researchers will be required to take the CITI Human Subject web-based course or equivalent.

The investigators will make all efforts to minimize the physical and psychological risks to human subjects. In regard to screening for study entry, patients' discovered to have a clinical/laboratory contraindication for PrEP will be informed and educated by the RA regarding the reason for their ineligibility. Clinical/laboratory abnormalities will be addressed using standard ED protocols. Patients with a primary care provider will be referred back to their doctor for further management. For patients without a primary care provider follow-up will depend on the specific exclusion criteria. Patients with decreased eCrCL will be referred to out-patient nephrology. Patients found to have HBsAg+ will be referred to out-patient Hepatology. Patients found to be HIV+ will be immediately linked to care at PKC as per standard ED protocols. Patients found to be pregnant will be referred to out-patient Obstetrics and Gynecology.

Data related risks are described below under privacy protections and data security and confidentiality. It is possible that patients may become anxious when responding to the risk factor questionnaires. RAs will receive extensive training on counseling patients for PrEP and addressing any patient concerns. If the RAs need additional assistance they will reach out to the PI.

Study protocol will be adhered to as indicated and approved by the Mount Sinai Institutional Review Board and compliance offices.

Consent procedure: Consent procedures are described in Section 9.2. Informed consent procedures for all participants or informants, with attention to literacy level of participants.

Privacy protections: All data obtained during this study will be kept strictly confidential. All hard copy information will be kept in a separate private research room, in a cabinet, under lock and key. A password protected and secured database will hold all computer data. Access to the data will only be open to the co-PIs, co-investigators, and the research associates.

Stopping rules: Given that this trial focuses on feasibility and acceptability of an FDA approved medication being used for its intended purpose in its indented population, no stopping rules are in place.

Disclosure of incidental findings: As discussed in protection against risk, patients who screen out for a medical related reason will be informed of the reason for ineligibility by the PI and be provided with out-patient follow-up for further management. Standard mechanism are in place to address the laboratory abnormalities we expect to find during the screening process.

Data security and confidentiality protections: In order to capture the highest quality data, we will use a web-based system with electronic validation. In addition, we will cross-validate the data for complex errors. Study data will be collected and managed using REDCap electronic data capture tools hosted at the Icahn School of Medicine at Mount Sinai.[75] REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

All study data will be entered in the electronic data capture (EDC) system. Study personnel requiring access will have their own Login/Password. Access to clinical study information will be based on individuals' roles and responsibilities. All study data will be transmitted over an encrypted SSL (Secure Sockets Layer) connection that requires user authentication. This application is designed to be in full compliance with the International ference on Harmonization and Good Clinical Practices (ICH-GCP), the FDA's Code of Federal Regulations) 21 Part 11 Electronic Record and Electronic Signatures, the FDA's "Guidance: Computerized Systems

Used in Clinical Trials," and the Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Reportable Events:
HIV acquired while the patient is taking PrEP is considered a serious adverse event and reported to the IRB within 24 hours. Any pregnancy occurring while on PrEP will be considered a serious adverse event and reported to the IRB within 24 hours.

Data Management, Analysis, and Quality Assurance:
Sources of information will come from the socio-demographic questionnaires, behavioral risk factor questionnaires, PrEP attitude and knowledge measures, satisfaction questionnaires, laboratory test results, adherence questionnaires, electronic medical records and VSQ-9 study visit questionnaires. As noted above all study data will be entered in the electronic data capture (EDC) system that requires unique user Login/Password.

The greatest threat to study validity is likely to be loss to follow-up. We have attempted to minimize this possibility by requiring detailed locator information and preforming facilitated linkage. The follow-up rate in our HCV screening program is 50% where there is no requirement for locator data or facilitated linkage. We expect the rates of follow-up in this program to be closer to 85% as was seen in Project BRIEF where facilitated linkage mechanisms were used. We will also collect short term (30-day) and longer term follow-up (60 & 90-days) data to ensure that, even if there is drop-out at each time point, we will still have usable data for outcome analysis.

Given that the study will examine patients presenting to one urban academic emergency department, the results may not generalize to other EDs. We do not see this as problematic as more widespread dissemination first requires some data on the impact of a PrEP screening, initiation and linkage program in the ED setting. We anticipate that the results from this study will set the foundations for a future multicenter R01 that will specific address generalizability.

18.0 ADVERSE EVENT REPORTING AND PROCEDURES

18.1 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.

18.2 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.

18.3 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.

18.4 Adverse Event Reporting

Appropriately qualified and trained personnel will elicit participant reporting of AEs and SAEs (Appendix 10) at each follow-up assessment. 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.

18.5 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.

18.6 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.

18.7 Guidelines for Determining Causality

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

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

18.8 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.

18.9 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 within the first 14-day and the patient was assigned to the iPrEP arm, the participant will be asked to complete an end-of-study medication visit to return unused medication and document end-of-medication outcomes.

19.0 Overall Structure of the Team

Research Team: The research team is comprised of experts in ED based public health program development and implementation. A project manager from the Mount Sinai Hospital Department of Emergency Medicine will provide administrative support. A TBN RA will undergo extensive training with the PI and the New York City Department of Health and Mental Hygiene (NYC DoHMH) to understand how to recruit, enroll and counsel the patients participating in this study. A TBN biostatistician will provide statistical support and analysis of the proposed studies.

Research Associate Training: RAs will undergo two weeks of training that includes both didactic course work and shadowing. The didactic course work is offered by the New York City Department of Health and Mental Hygiene through the Training and Technical Assistance Program. Required courses for the RAs will include Understanding HIV infection, diagnosis and treatment (1-day), PEP, PrEP and Other Biomedical Interventions (1-day), Best Practices in PrEP/PEP Education & Counseling (1-day), Fundamentals of HIV Prevention Counseling (2-days) and Motivational Interviewing (2-day) and Improving linkage to care using the "ARTAS" model (2-days).[76] Didactic training will occur in the first two months of the grant. RAs will shadow Dr. Salomon for 1 week prior to the start of the RCT to familiarize themselves with linkage pathways and mechanisms, PrEP counseling, adherence counseling and risk reduction counseling

20.0 Interventions

Intervention Type	Randomized Controlled Clinical Trial
Name	Pre-Exposure Prophylaxis Provision in the Emergency Department (PrEPPED Trial)
Description	Compare the impact of immediate PrEP initiation in the Emergency Department by providing a PrEP "starter pack" with facilitated linkage to care versus facilitated linkage to care for out-patient PrEP initiation within 14 days of the Emergency Department visit.

21.0 Outcome measures

Secondary Outcome 1:	Retention in PrEP care at 30, 60, and 90 days post PrEP index visit
Type	Secondary
Time frame	30, 60 and 90 days
Brief description	# of patients retained in care at 30, 60 and 60-days post-PrEP initiation

Secondary Outcome 2:	PrEP usage post PrEP index visit

Type	Secondary
Time frame	30, 60 and 90 days
Brief description	# of patients still using PrEP at 30 and 60-days post PrEP initiation

Secondary Outcome 3:	PrEP adherence at follow up post PrEP index visit
Type	Secondary
Time frame	30, 60, 90 days
Brief description	Level of adherence to PrEP at 30, 60, 90-days post PrEP initiation

Secondary Outcome 4:	Risk behavior post PrEP index visit
Type	Secondary
Time frame	30, 60, 90 days
Brief description	HIV risk behaviors at 30, 60, 90-days post PrEP initiation

Secondary Outcome 5:	STI diagnoses post PrEP index visit
Type	Secondary
Time frame	30, 60, 90 days
Brief description	# and type of STI diagnosed at 30 and 90-day post PrEP initiation visits

Secondary Outcome 6:	HIV infection
Type	Secondary
Time frame	90-days
Brief description	# of new HIV infections, if any, at 90-days post PrEP initiation

Secondary Outcome 7:	Program Satisfaction
Type	Secondary
Time frame	90-days
Brief description	Program satisfaction at 30, 60 and 90-day follow-up

22.0 FDA Regulated Intervention

For this intervention, we do not require an Investigational New Drug application to the FDA. Emtricitabine/tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide are both FDA approved for Pre-Exposure Prophylaxis for HIV and meet all of the requirements for an IND exemption as described in 21 CFR 312.2(b). These include:

1) The drug product is lawfully marketed in the United States.
2) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
3) In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
4) The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product (21 CFR 312.2(b) (1) (iii)).
5) The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).
6) The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).

23.0 Dissemination Plan

23.1 Clinicaltrials.gov Requirements

This project includes applicable clinical trials which require registration in ClinicalTrials.gov. In accordance with Public Law 110-85 the trials will be registered with clinicaltrials.gov prior to the enrollment of the first participant. Reporting of summary results will occur no later than 1 year after the completion date of the last enrolled participant. All grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov. The responsible party for all clinicaltrials.gov reporting will be the PI, Dr. Cowan.

23.2 Informed consent

A description of this clinical trial will be available on the website, http://www.ClinicalTrials.gov, as required by U.S. Law. The National Institutes of Health (NIH) encourages all researchers to post their research. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.

23.3 Translation Plan

We plan on publishing 3-5 manuscripts in peer-reviewed health science journals to disseminate the results of the proposed project and present our findings at professional conferences both regionally and nationally. Once this study is completed and data analyzed we will submit and R01 for a multicenter RCT to provide definitive evidence regarding the impact of an emergency department-based program for PrEP screening, initiation and linkage program in the ED setting.

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Effective Date: 4/20/2021
End Date: 3/18/2022

APPENDIX

Appendix 1: Locator Form

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?
Yes ❑ (skip to Q6)
No ❑ (complete address below)
Address _____
_____ Apt No.: _____
City _____ State _____ Zip Code: _____

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: ❑ _____

8. OK to text primary number? ❑ Yes ❑ No

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

10. 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
14. 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
15. 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 2: Satisfaction Measure

Exposure Prophylaxis Provision in the Emergency Department (PrEPPED)
action and Acceptability Measures

ıll 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

Appendix 3: Attitudes Towards PrEP

Attitudes toward future PrEP usage

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

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

Would you be interested in starting PrEP 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

What do you think about an oral HIV prevention method?
What do you think you might like about an oral method? *Check all that apply.*

☐ Nothing

☐ May protect against HIV

☐ Easier to use than other methods (e.g., condoms)

☐ Can be used discreetly, without a partner's knowledge

☐ Does not interrupt sex

☐ Easily reversible

☐ Other, specify: _____

☐ Prefer not to answer

What concerns do you have about an oral HIV prevention method?

☐ None

☐ May not protect against HIV

☐ May cause harmful side effects

☐ Requires taking a daily pill

☐ Cannot be used discreetly, without a partner's knowledge

☐ Cost may be unaffordable

☐ Other, specify: _____

☐ Prefer not to answer

Appendix 4: CSBQ

CDC Sexual Behavior Questions (CSBQ)
FIRST TIER QUESTIONS
The next questions are about your sexual behavior. By sex we mean oral, vaginal, or anal sex, but NOT masturbation. When we talk about condoms, we mean both male as well as female condoms.

1. During the past 12 months, have you had sex?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END
[NHSDA]

2. During the past 12 months, with how many people have you had sex?
Number [...] Don't know / Not sure [enter 777] Refused [enter 999]
[BRFSS; NHSDA]

3. During the past 12 months, have you had sex with only males, only females, or with both males and females?
Only males [1] Only females [2] Both males and females [3] Refused [9]
[NHSDA]

w, thinking back about the last time you had sex, did you or your partner use a condom? Yes [1] No [2] ed [9]

[NHSDA; BRFSS; YRBS]

5. I'm going to read you a list. When I'm done, please tell me if any of the situations apply to you. You don't need to tell me which one.
You have used intravenous drugs in the past year You have been treated for a sexually transmitted disease or venereal disease in the past year You tested positive for having HIV, the virus that causes AIDS You have had more than one sex partner in the past year During the past 12 months you have given or received money or drugs in exchange for sex

Do any of these situations apply to you?

Yes [1] No [2] Refused [9]
[BRFSS, adapted]

END OF FIRST TIER QUESTIONS

ALTERNATE FIRST TIER QUESTIONS

The next questions are about your sexual behavior. By sex we mean oral, vaginal, or anal sex, but NOT masturbation. When we talk about condoms, we mean both male as well as female condoms.

1. During the past 12 months, have you had sex?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END
[NHSDA]

2. During the past 12 months, with how many people have you had sex?
Number [...] Don't know / Not sure [enter 777] Refused [enter 999]
[BRFSS; NHSDA]

3. During the past 12 months, have you had sex with only males, only females, or with both males and females?
Only males [1] Only females [2] Both males and females [3] Refused [9]
[NHSDA]

4. I'm going to read you a list. When I'm done, please tell me if any of the situations apply to you. You don't need to tell me which one.
You have used intravenous drugs in the past year You have been treated for a sexually transmitted disease or venereal disease in the past year You tested positive for having HIV, the virus that causes AIDS You have had more than one sex partner in the past year During the past 12 months you have given or received money or drugs in exchange for sex
Do any of these situations apply to you?

Yes [1] No [2] Refused [9]
[BRFSS, adapted]

The next questions are about sex with a main partner.

5. In the past 12 months have you had sex with someone who you consider to be your main sex partner, that is a
er who you feel committed to above anyone else?
1] No [2] SKIP to QUESTION 8 Refused [9] SKIP to QUESTION 8
DA- Adapted]

If you had more than one main partner during the past 12 months, we would like you to think of the main partner you had last sex with.
6. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]

7. Now, thinking back about the last time you had sex, did you or your partner use a condom?
Yes [1] No [2] Refused [9]
[NHSDA; BRFSS; YRBS]

8. In the past 12 months, have you had sex with someone who is not your main partner or whom you did not consider to be your main partner at the time?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END
For the next series of questions, think back to the last time you had sex with someone who is/was not your main partner.
9. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]

10. Now, thinking back about the last time you had sex, did you or your partner use a condom?
Yes [1] No [2] Refused [9]
[NHSDA; BRFSS; YRBS]
END OF ALTERNATE FIRST TIER QUESTIONS

SECOND TIER QUESTIONS

The next questions are about your sexual behavior. By sex we mean oral, vaginal, or anal sex, but NOT masturbation. When we talk about condoms, we mean both male as well as female condoms.

1. During the past 12 months, have you had sex?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END
[NHSDA]
2. During the past 12 months, with how many people have you had sex?
Number [...] Don't know / Not sure [enter 777] Refused [enter 999]
[BRFSS; NHSDA]

3. During the past 12 months, have you had sex with only males, only females, or with both males and females?
Only males [1] Only females [2] Both males and females [3] Refused [9]
[NHSDA]

4. During the past 12 months, has a doctor or other health professional told you that you had a sexually transmitted disease, or STD, for example, herpes, gonorrhea, chlamydia, genital warts?
Yes [1] No [2] Don't know / Not sure [7] Refused [9]
[HITS]
5. Have you ever been told by a doctor of other health professional that you were infected with HIV or that you have AIDS?
Yes [1] No [2] Don't know / Not sure [7] Refused [9] [RBA, adapted]

6. During the past 12 months, have you given drugs in exchange for sex or received drugs in exchange for sex ?
x we mean vaginal, oral, or anal sex.
1] No [2] Refused [9]
DA]

7. During the past 12 months, have you given money in exchange for sex or received money in exchange for sex? By sex we mean vaginal, oral, or anal sex.
Yes [1] No [2] Refused [9]
[NHSDA; Some surveys have combined questions 6 and 7, for example: In the past 12 months, have you given or taken money or drugs in exchange for sex? (NHIS-Supplement)]
If respondent is female: SKIP to SECOND TIER QUESTION 26
[MALE RESPONDENTS ONLY]
The next questions are about sex with a main partner.
8. In the past 12 months have you had sex with someone who you consider to be your main sex partner, that is a partner who you feel committed to above anyone else?
Yes [1] No [2] SKIP to QUESTION 42 Refused [9] SKIP to QUESTION 42
[NHSDA- Adapted]

If you had more than one main partner during the past 12 months, we would like you to think of the main partner you had last sex with.

9. When was the first time you had sex with your main partner?
__ __/__ __ __ __ (month/year)

10. When was the last time you had sex with your main partner?
__ __/__ __ __ __ (month/year)
11. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]
**If partner is male (Question 11= 1), then SKIP to QUESTION 16
12. The last time you had sex with your main partner, did you have vaginal sex, where your penis entered your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 14 Refused [9] SKIP to QUESTION 14
13. Was a condom used?
Yes [1] No [2] Refused [9]

14. The last time you had sex with your main partner, did you have oral sex, where your mouth touched your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 16 Refused [9] SKIP to QUESTION 16
15. Was a barrier (dental dam, plastic wrap, etc) used?
Yes [1] No [2] Refused [9]
16. The last time you had sex with your main partner, did you have oral sex, where your penis entered your partner's mouth?
Yes [1] No [2] SKIP to QUESTION 18 Refused [9] SKIP to QUESTION 18
17. Was a condom used?
Yes [1] No [2] Refused [9]

18. The last time you had sex with your main partner, did you have anal sex, where your penis entered your partner's anus (butt)?
Yes [1] No [2] SKIP to QUESTION 20 Refused [9] SKIP to QUESTION 20
19. Was a condom used?
Yes [1] No [2] Refused [9]
**If main partner is female (Question 11 = 2) , then SKIP to QUESTION 24 **
[illegible]e last time you had sex with your main partner did you have anal sex where your partner's penis entered [illegible]anus (butt)?
[illegible]1] No [2] SKIP to QUESTION 22 Refused [9] SKIP to QUESTION 22
[illegible]as a condom used?

Yes [1] No [2] Refused [9]
22. The last time you had sex with your main partner, did you have oral sex, where your partner's penis entered your mouth?
Yes [1] No [2] SKIP to QUESTION 24 Refused [9] SKIP to QUESTION 24
23. Was a condom used?
Yes [1] No [2] Refused [9]

24. The last time you had sex with your main partner, were you under the influence of alcohol? Yes [1] No [2] Refused [9] [modified from NHSLS]

25. The last time you had sex with your main partner, had you been using drugs to get high before or during sex?
Yes [1] SKIP to QUESTION 42 No [2] SKIP to QUESTION 42 Refused [9] SKIP to QUESTION 42
[modified from NHSLS]
[FEMALE RESPONDENTS]
The next questions are about sex with a main partner.
26. In the past 12 months have you had sex with someone who you consider to be your main sex partner, that is a partner who you feel committed to above anyone else?
Yes [1] No [2] SKIP to QUESTION 60 Refused [9] SKIP to QUESTION 60
[NHSDA- Adapted]

27. When was the first time you had sex with your main partner?
__ __/__ __ __ __ (month/year)

28. When was the last time you had sex with your main partner?
__ __/__ __ __ __ (month/year)
29. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]
If partner is female (Question 29 = 2), then SKIP to QUESTION 36

30. The last time you had sex with your main partner, did you have vaginal sex, where your partner's penis entered your vagina?
Yes [1] No [2] SKIP to QUESTION 32 Refused [9] SKIP to QUESTION 32

31. Was a condom used?
Yes [1] No [2] Refused [9]
32. The last time you had sex with your main partner, did you have oral sex, where your partner's penis entered your mouth?
Yes [1] No [2] SKIP to QUESTION 34 Refused [9] SKIP to QUESTION 34
33. Was a condom used?
Yes [1] No [2] Refused [9]
34. The last time you had sex with your main partner, did you have anal sex, where your partner's penis entered your anus (butt)?
Yes [1] No [2] SKIP to QUESTION 36 Refused [9] SKIP to QUESTION 36

35. Was a condom used?
1] No [2] Refused [9]
e last time you had sex with your main partner, did you have oral sex, where your partner's mouth
ed your vagina?
1] No [2] SKIP to QUESTION 38 Refused [9] SKIP to QUESTION 38

37. Was a barrier (dental dam, plastic wrap, etc) used?
Yes [1] No [2] Refused [9]
If partner is male (Question 29 = 1), then SKIP to QUESTION 40

38. The last time you had sex with your main partner, did you have oral sex, where your mouth touched your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 60 Refused [9] SKIP to QUESTION 60

39. Was a barrier (dental dam, plastic wrap, etc) used?
Yes [1] No [2] Refused [9]

40. The last time you had sex with your main partner, were you under the influence of alcohol? Yes [1] No [2] Refused [9] [modified from NHSLS]
41. The last time you had sex with your main partner, had you been using drugs to get high before or during sex?
Yes [1] SKIP to QUESTION 60 No [2] SKIP to QUESTION 60 Refused [9] SKIP to QUESTION 60
[modified from NHSLS]
[MALE RESPONDENTS ONLY]
The next series of questions are about sex with someone who is/was not your main partner.
42. In the past 12 months, have you had sex with someone who is not your main partner or whom you did not consider to be your main partner at the time?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END

For the next series of questions, think back to the last time you had sex with someone who is/was not your main partner.

43. When was the first time you had sex with this partner?
__ __/__ __ __ __ (month/year)

44. When was the last time you had sex with this partner?
__ __/__ __ __ __ (month/year)

45. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]

If partner is male (Question 45 = 1), then SKIP to QUESTION 50
46. The last time you had sex with this partner, did you have vaginal sex, where your penis entered your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 48 Refused [9] SKIP to QUESTION 48
47. Was a condom used?
Yes [1] No [2] Refused [9]

48. The last time you had sex with this partner, did you have oral sex, where your mouth touched your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 50 Refused [9] SKIP to QUESTION 50

'as a barrier (dental dam, plastic wrap, etc) used?
1] No [2] Refused [9]
he last time you had sex with this partner, did you have oral sex, where your penis entered your partner's
n? Yes [1] No [2] SKIP to QUESTION 52 Refused [9] SKIP to QUESTION 52

51. Was a condom used?
Yes [1] No [2] Refused [9]

52. The last time you had sex with this partner, did you have anal sex, where your penis entered your partner's anus (butt)?
Yes [1] No [2] SKIP to QUESTION 54 Refused [9] SKIP to QUESTION 54
53. Was a condom used?
Yes [1] No [2] Refused [9]
If partner is female (Question 45 = 2), then SKIP to QUESTION 58.

54. The last time you had sex with this partner did you have anal sex where your partner's penis entered your anus (butt)?
Yes [1] No [2] SKIP to QUESTION 56 Refused [9] SKIP to QUESTION 56

55. Was a condom used?
Yes [1] No [2] Refused [9]

56. The last time you had sex with this partner, did you have oral sex, where your partner's penis entered your mouth?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END

57. Was a condom used?
Yes [1] SKIP to END No [2] SKIP to END Refused [9] SKIP to END

58. The last time you had sex with this partner, were you under the influence of alcohol? Yes [1] No [2] Refused [9] [modified from NHSLS]
59. The last time you had sex with this partner, had you been using drugs to get high before or during sex?
Yes [1] SKIP to END No [2] SKIP to END Refused [9] SKIP to END
[modified from NHSLS]
[FEMALE RESPONDENTS]
The next series of questions are about sex with someone who is/was not your main partner.
60. In the past 12 months, have you had sex with someone who is not your main partner or whom you did not consider to be your main partner at the time?
Yes [1] No [2] SKIP to END Refused [9] SKIP to END
61. When was the first time you had sex with your main partner?
__ __/__ __ __ __ (month/year)

62. When was the last time you had sex with your main partner?
__ __/__ __ __ __ (month/year)

63. Is this person a man or a woman?
Man [1] Woman [2] Refused [9]

If partner is female (Question 63 = 2), then SKIP to QUESTION 70.
64. The last time you had sex with this partner, did you have vaginal sex, where your partner's penis entered your vagina?
Yes [1] No [2] SKIP to QUESTION 66 Refused [9] SKIP to QUESTION 66

'as a condom used?
1] No [2] Refused [9]

66. The last time you had sex with this partner, did you have oral sex, where your partner's penis entered your mouth?
Yes [1] No [2] SKIP to QUESTION 68 Refused [9] SKIP to QUESTION 68

67. Was a condom used?
Yes [1] No [2] Refused [9]

68. The last time you had sex with this partner, did you have anal sex, where your partner's penis entered your anus (butt)?
Yes [1] No [2] SKIP to QUESTION 70 Refused [9] SKIP to QUESTION 70
69. Was a condom used?
Yes [1] No [2] Refused [9]
70. The last time you had sex with this partner, did you have oral sex, where your partner's mouth touched your vagina?
Yes [1] No [2] SKIP to QUESTION 72 Refused [9] SKIP to QUESTION 72

71. Was a barrier (dental dam, plastic wrap, etc) used?
Yes [1] No [2] Refused [9]

If partner is male (Question 63 =1), then SKIP to QUESTION 74.

72. The last time you had sex with this partner, did you have oral sex, where your mouth touched your partner's vagina?
Yes [1] No [2] SKIP to QUESTION 74 Refused [9] SKIP to QUESTION 74
73. Was a barrier (dental dam, plastic wrap, etc) used?
Yes [1] No [2] Refused [9]

74. The last time you had sex with this partner, were you under the influence of alcohol?
Yes [1] No [2] Refused [9]
[modified from NHSLS]
75. The last time you had sex with this partner, had you been using drugs to get high before or during sex?
Yes [1] No [2] Refused [9]
[modified from NHSLS]

Appendix 5: PrEP Screening for Substantial Risk and Eligibility (ICAP)

Pre-Exposure Prophylaxis (PrEP) Screening for Substantial Risk and Eligibility

1. Facility Information	
Facility Name	
Date of Initial Client Visit *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __	Person Completing Form

2. Client Information		
t Name	Middle Name	Surname
ress	Telephone #	

Client ID Number

3. Client Demographics	
What was your sex at birth?	☐ Male ☐ Female ☐ Other *(specify):* _____ ☐ No response
What is your current gender?	☐ Male ☐ Female ☐ Transgender *(male to female)* ☐ Transgender *(female to male)* ☐ Other *(specify):* _____ ☐ No response
What is your age? *(Specify number of years.)*	_____

4. Screening for Substantial Risk for HIV Infection	
Client is at substantial risk if he/she belongs to categories ❶, ❷, or ❸ *below*	**Question Prompts for Providers**
❶ **If client is sexually active in a high HIV prevalence population <u>PLUS</u> reports ANY one of the below in the last <u>6 months</u>**	Have you been sexually active in the last 6 months?
☐ Reports vaginal or anal intercourse without condoms with more than one partner	In the last 6 months, how many people did you have vaginal or anal sex with? In the last 6 months, did you use condoms consistently during sex?
☐ Has a sex partner with one or more HIV risk:	In the last 6 months, have you had a sex partner who: • Is living with HIV? • Injects drugs? • Has sex with men? • Is a transgender person? • Is a sex worker? • Has sex with multiple partners without condoms?

☐ History of a sexually transmitted infection (STI) *based on self-report, lab test, syndromic STI treatment*	In the last 6 months, have you had an STI?
☐ History of use of post-exposure prophylaxis (PEP)	In the last 6 months, have you taken post-exposure prophylaxis (PEP) following a potential exposure to HIV?
❷ **If client reports history of sharing injection material or equipment in the last 6 months** ☐ History of sharing injection material or equipment	In the last 6 months, have you shared injecting material with other people?
❸ **If client reports having a sexual partner in the last 6 months who is HIV positive AND who has not been on effective* HIV treatment** (i.e., the partner has been on ART for fewer than 6 months or has inconsistent or unknown adherence) ☐ History of HIV-positive sex partner not on effective treatment	Is your partner HIV positive? Is he/she on ART? What was the last viral load result?

5. PrEP Eligibility

Client is eligible if he/she fulfills ALL the criteria below:	
☐ **HIV negative**	**Date client tested:** *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __ **Date client received test results:** *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __ **Test result:** ☐ Negative ☐ Positive *(Refer to HIV medical care.)* ☐ Inconclusive *(Re-test in 14 days.)*

	Type of test used: ☐ Determine ☐ Unigold ☐ ELISA ☐ Other *(specify):*
☐ **At substantial risk of HIV**	At least one item/risk in Section #4 above is ticked
☐ **Has no signs/symptoms of acute HIV infection**	See Section #6 below to confirm no recent exposure to HIV
☐ **Has creatinine clearance (eGFR) >60 ml/min**	Result: _____ Date of creatinine test *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

If all boxes in Section 5 are ticked, offer PrEP.

6. Recent Exposure to HIV

Ask the client: In the past 72 hours, have you had sex without a condom with someone whose HIV status is positive or not known to you, or have you shared injection equipment with someone whose HIV status is positive or unknown to you?	☐ **Yes***	☐ No	☐ Don't know
In the past 28 days, have you had symptoms of a cold or flu, including fever, fatigue, sore throat, headache, or muscle pain or soreness?	☐ **Yes** **	☐ No	☐ Don't know

* **If the client reports potential exposure to HIV within past 72 hours, do NOT offer PrEP. Follow facility procedures to evaluate further or refer for evaluation for post-exposure prophylaxis (PEP).**

** **If the client reports flu-like symptoms or other signs of acute HIV infection, do NOT offer PrEP and evaluate further, following facility procedures to diagnosis acute HIV infection.**

7. Services Received by Client

☐ **PrEP offered.**

- ☐ **PrEP accepted.**
- ☐ **PrEP declined.** (*If declined, see* Reasons for Declining PrEP, *below).*

Date eligible *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __

Date initiated *(dd/mm/yyyy):* __ __ /__ __ /__ __ __ __ *Same-day initiation recommended.*

Reasons for Declining PrEP

(Check all that apply.)

- ☐ **No need for PrEP**
- ☐ **Does not wish to take a daily medication**
- ☐ **Concerns about side effects**
- ☐ **Concerns about what others might think**
- ☐ **Concerns about time required for clinic follow-up**
- ☐ **Concerns about safety of medication**
- ☐ **Concerns about effectiveness of medication**
- ☐ **Other** *(specify):*

☐ **Referred for PEP evaluation**

☐ **Referred for PCR/HIV Ag test or follow-up HIV re-testing (if suspicion of acute HIV infection)**

Appendix 6: VSQ-9

Patient Satisfaction Survey

Thinking about your visit with the physician/health care Professional you aw, how would you rate the following:

	Poor	Fair	Good	Very Good	Excellent
1. How long you waited to get an appointment	O	O	O	O	O
2. Convenience of the location of the office	O	O	O	O	O
3. Getting through to the office by phone	O	O	O	O	O
4. Length of time waiting at the office	O	O	O	O	O
5. Time spent with the physician/health care professional you saw	O	O	O	O	O
6. Explanation of what was done for you	O	O	O	O	O
7. Technical skills (thoroughness, carefulness, competence) of the physician/health care professional you saw	O	O	O	O	O
8. The personal manner (courtesy, respect, sensitivity, friendliness) of the person you saw	O	O	O	O	O
9. The visit overall	O	O	O	O	O

Appendix 7: GRIP

Excellent	Very Good Good	Fair	Poor Very Poor
Identify/remind patient about available adherence support resources	Offer opportunity to use/participate in 1 or more available adherence support interventions	Recommend use of/participation in 1 or more available adherence support interventions	Strongly recommend use of/participation in 1 or more available adherence support interventions

Appendix 8: 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 9: Authorized Release 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. # _____ S.S. # _____

Street, Apt # _____

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 10: Adverse Event Reports

rse Event Report (AD1)

rse Event Onset Date:

nce 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:

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

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

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

- ☐ Tolerable
- ☐ Distressing

2. HEART

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

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

- ☐ Tolerable
- ☐ Distressing

3. SKIN

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

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

- ☐ Tolerable
- ☐ Distressing

4. NERVOUS SYSTEM

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

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

- ☐ Tolerable
- ☐ Distressing

5. EYES/EARS

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

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

- ☐ Tolerable
- ☐ Distressing

6. GENITAL/URINARY

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

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

- ☐ Tolerable
- ☐ Distressing

CRC ID ☐☐☐☐☐☐☐☐☐☐

Effective Date: 4/20/2021
End Date: 3/18/2022