# I. STUDY IDENTIFICATION INFORMATION

**TITLE OF PROTOCOL**: Emergency Department Longitudinal Integrated Care 2.0 (ED-LINC 2.0)

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**FUNDER OF PROTOCOL: National Institute of Drug Abuse (NIDA)**

**CLINICALTRIALS.GOV:** A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. ***NCT03699085***

**SAP Version date:** September 2021

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Summary of Clinical Trial Features:

The *Emergency Department Longitudinal Integrated Care* (ED-LINC) intervention is a stepped collaborative care model of care initiated from the ED for patients with OUD that combines evidence-based treatment elements, proactive care coordination and population-level outcome tracking. ED-LINC builds upon previous work by tailoring the collaborative care model for patients at high risk for OUD presenting to the ED. A central objective of ED-LINC is to provide evidence-based treatment for OUD and related co-morbidity while in the ED in conjunction with proactive longitudinal care coordination that links patients to ongoing treatment. Weekly caseload supervision with measurement-based care outcome tracking allows for the stepping up of care for patients with recalcitrant symptoms, as well as opportunities to oversee care management linkages to community services targeting the key outcomes of initiation of MOUD and retention in MOUD treatment.

The main objective of this study was to conduct a pilot pragmatic randomized clinical trial of ED-LINC (n=20) compared to usual care (n=20) for ED patients at a single-site at high risk for OUD. The primary outcomes of this study pertain to feasibility of the model, research strategy and implementation.

Primary Outcome Measures

All primary outcome measures used **descriptive statistics**

Refusal Rate was calculated as the number of patients that refused or declined the self-report screening procedure in the ED divided by the eligible number of patients that could have done the self-report screening during the enrollment period.

Follow-up Completion Rates were calculated for each followup timepoint and were calculated as the number of participants that completed follow-up divided by the total number of participants randomized to each arm of the trial. The 6-month followup completion rate is shown as the number of participants that completed the 6-month self-report interview divided by the number of participants randomized to each arm.

ED-LINC Intervention and usual Care process Outcomes were determined from extensive research notes. Specifically the EDLINC interventionist conducted a process validity assessment and documented the number of unique ED-LINC elements completed for each participant in the intervention.

Implementation Appropriateness was calculated by providing this validated self-report measure to each participant randomized to the ED-LINC assessment. Results were dichotomized to calculate the frequency of participants who ‘agreed’ or ‘completely agreed’ that the intervention was ‘applicable’ and ‘seemed like a good match’ to document appropriateness.

Satisfaction was calculated using a validated satisfaction questionnaire and provided to all participants at six-months. Each participant will complete the questionnaire and their results will be summed. The median and IQR range will be calculated for participants in each group that complete the assessment.

Perception of Care Coordination will be done using questions from a validated scale. The Wilcoxon Rank Sum test will be used to determine if there are significant differences between groups.

Secondary Outcome Measures

**Substance Use**

Substance use will be measured using the timeline follow back procedure which is a validated calendar method to determine days of use in a certain calendar period. First, we will sum days of use of illicit opioid use in 30 days at baseline and each followup period for each participant. The mean days of use/30 days with an associated standard deviation will be calculated at each time-period for both the ED-LINC intervention and the usual care control groups.

Next, we will evaluate variance of the data and test model fit on unadjusted data using different distributions. Given previous work, we anticipate the data to be skewed and zero-inflated. Thus, we hypothesize that we may use a normal Gaussian, Poisson or negative binomial distribution.

Once model fit is determined, a reverse stepwise selection will be performed using a linear regression of clinician-selected input variables, alongside the intervention and TLFB timepoint, and an elimination threshold of $p > 0.05$