Study: # 7764 entitled An Open-Label Pilot Study of Sublocade as Treatment for Opiate Use Disorder

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C. DATA MANAGEMENT AND ANALYSIS

C1. Data Acquisition and Transmission

All data will be obtained specifically for research purposes. Data will be entered into an Excel spreadsheet coded with a unique identifier assigned to each participant. Departmental, HIPAA-compliant Research Subject Registration System, will however contain participants' names.

C2. Data Entry Methods

As noted above, data will be entered into an Excel spreadsheet. Data management will include: 1) protocol management; 2) patient scheduling; 3) regulatory reporting and 4) management of research organizations, personnel, and collaborators. The research staff will collect and input data on a daily, basis to reduce the likelihood of errors. Information collection and analysis and study-specific data collection will be easily retrievable, organized, and reviewed on an ongoing basis as well.

C3. Data Analysis Plan

Overview of Data Analytic Plan

Sample size: A total of 10 participants will be recruited.

A total of 10 patients will be recruited over a 6-month period. The main analyses in this study will be on the intent-to-treat (ITT) sample, i.e. on all enrolled patients who receive study medication, and all tests will be two-sided, performed at significance α=0.05, except where noted. Before specific statistical techniques are applied in order to test the hypotheses of interest, we will examine all variables at all time points for outliers. The distributions of all continuous variables will be checked for normality, and transformations will be employed, if necessary, before applying specific parametric techniques.

Hypotheses testing:

Primary Outcome: The proportion of participants successfully inducted onto BXR.

Secondary Outcomes: BXR treatment will be associated with decreased opioid use for OUD patients positive for HPSO. The primary outcome measure will be opioid use during the last two weeks of the study compared to baseline as measured by a combination of urine toxicology and self-report. BXR injection will be associated with reduce symptoms of craving and symptoms of withdrawal as compared to baseline.