NYSPI Protocol Number: 7475

Protocol Title: Effect of Lorcaserin on Cannabis Withdrawal and Self-administration

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<u>Data Analysis Plan</u>

Repeated measures analyses of variance including two within-subject factors (medication dose, and inpatient day) with planned comparisons were used to determine the effects of lorcaserin, relative to placebo, on (primary outcome) cannabis self-administration under abstinent and non-abstinent conditions and (secondary outcome) subjective effects following controlled cannabis administration. Other secondary outcomes included the following: number of cannabis puffs that were self-administered, daily peak subjective-effects ratings, drug craving, objective and subjective sleep measures, food intake (total energy intake, percent macronutrient [fat, protein, and carbohydrate]), body weight, blood pressure and heart rate. Significance was determined at $\alpha = 0.02$. Huynh–Feldt corrections were used. Note that repeated-measures, within-subject designs result in substantial correlations between levels and are a powerful statistical approach. Based on a previous study from our group, a sample size of 15 study completers provides >90% power to detect changes in cannabis self-administration and subjective effects as a function of lorcaserin versus placebo. Effects of lorcaserin on the frequency of side effects were assessed using sign test, a nonparametric test used to identify consistent differences between pairs of observations (lorcaserin vs. placebo).