

## PROTOCOL TITLE:

# High Frequency Oscillation in Pediatric Epilepsy Surgery

Protocol Version Date: 26 Oct 2017

**NCT03790280**

### **Statistical Analysis Plan (SAP):**

Our primary comparisons will be the comparison of post-surgery seizure free-time between the SOC and SOC+HFO study arms. The primary analysis will be a log-rank test. The secondary analysis of the primary endpoint will be a Cox-proportional hazards regression with seizure-free survival time as the outcome. Covariates will be treatment, and subject-level characteristics (ex. age and gender). Secondary outcomes of 2-year seizure-free rate will be assessed with logistic regression models using a similar set of covariates that will be included in the Cox model. Surgical complication rates will be compared using Fisher's exact tests for the overall analysis. The intent-to-treat principal will be utilized and subjects will be included in the randomized study arms for analysis rather than the actual treatment received. We will conduct a secondary analysis based on treatment received.