

**Principal Investigator:** Amy D. DiVasta, MD

**Protocol Title:** Novel Treatments for Endometriosis (NOTE): Dopamine Receptor Agonist Therapy for Pain Relief in Women Suffering from Endometriosis Pilot Study

**IRB Number:** RB-P00018628

**NCT Number:** NCT02542410

**Document Date:** June 11, 2019

### Statistical Plan

The **primary test of interest** for the trial is a comparison of the mean change in pain score, as measured by the BPI, between groups over time. A linear mixed-effects model will be used to estimate the change over time within each group; the model will include fixed effects for group, time, and the group by time interaction and random effects for subject and time (to account for the correlation among observations from the same subject). Estimates and 95% confidence intervals for group differences at each time point will be created using linear contrasts. This pilot study is not designed to determine statistical superiority or equivalence of norethindrone acetate versus cabergoline; rather, the estimates obtained from the mixed model will be used to plan a future randomized controlled trial. **Secondary endpoints** will be analyzed similarly.

**Sample Size:** As the proposed investigation is a pilot study, the sample size has been chosen to provide estimates for the change over time in each group while minimizing the number of subjects exposed to the study treatments. Assuming that we will have an 80% trial completion rate, we will recruit 7 patients to each arm in order to have 5 completers in each randomization group.