

**PARTNERS HUMAN RESEARCH COMMITTEE
STATISTICAL ANALYSIS PLAN**

Title: Mechanisms of Pharyngeal Collapse in Sleep Apnea

Title of the study: Effect of Added Varnum Mouthpiece on Pharyngeal Collapsibility and Sleep Apnea Severity in Mouth Breathers

NTC: NCT02738255

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VI. BIOSTATISTICAL ANALYSIS

Part F (oral breathing):

Patients participating in the study are OSA patients with self-reported mouth breathing as well as nose breathers. They will be studied for baseline and device night in random order. The main outcomes are: 1. improvement in sleep apnea severity as quantified by apnea-hypopnea index, 2. improvement in pharyngeal collapsibility as quantified by peak airflow.

Power Calculations: We will plan to enrol 30 individuals. With an anticipated failure rate of 20% (due to insufficient sleep in the lab environment or difficulty tolerating the monitoring equipment, etc), this should yield a total of 24 subjects for analysis. We expect that 67% of the population will respond to this therapy, such that 16 patients will have improved sleep and reduced AHI. This sample size is designed to have >80% power to detect an effect size of $1.5 \times \text{S.D.}$ higher peak inspiratory flow (with device versus baseline). There is greater statistical power for the other comparisons.