

## **Summary**

## An Eight-Week Double-Blind, Randomized, Placebo-Controlled, Cross-Over Study Evaluating the Efficacy of a Natural Sleep Aid

**Protocol Number:** 3982ABRI1015

**Sponsor:** American Behavioral Research Institute

Table 6.0 Subjective Questionnaire - Consumer Perception - Comparison to Baseline

Table of Subjective Questionnaire Consumer refrequent Comparison to Susceme							
		Time Point	n	Relaxium Sleep (Product A)			
Qı	uestion			Mean	Number of Subject Improved From BL	Mean Percent Improvement From BL mean	P-Value TX vs. BL
1.	I sleep soundly and without interruption.	Baseline	30	4.23 ± 0.67			
		Week 4	30	3.10 ± 1.18	20 <mark>(66.7%)</mark>	24.44%	<0.001*
2.	. I am able to fall asleep easily.	Baseline	30	$4.10 \pm 0.60$			
		Week 4	30	2.83 ± 1.08	22 <mark>(73.3%)</mark>	29.44%	<0.001*
3.	I wake up feeling refreshed.	Baseline	30	4.13 ± 0.43			
		Week 4	30	2.63 ± 0.92	26 <mark>(86.7%)</mark>	35.66%	<0.001*

<sup>\*</sup>Indicates a statistically significant improvement compared to baseline, p $\leq$ 0.05

## **Conclusion:**

Under the conditions of this study, use of <u>Relaxium Sleep #57431-00301</u> as-directed by Sponsor revealed statistically significant improvements in sleep latency and sleep hours as well as statistically significant improvement in consumer perceptions of the ability to fall asleep and sleep quality.