

## **Rapid Response Characterization of New and Manipulated Tobacco Products**

Consumer Acceptability Testing of New and Manipulated Tobacco Products (Project 2)

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### Abstract:

We recognize that toxicity is just one aspect of the potential of tobacco products to produce harm. Public health is also affected by whether the characteristics of products are likely to increase uptake of tobacco, impede or delay tobacco use cessation, or promote return to use after cessation. Project II will inform FDA regulatory authority by characterizing and contrasting consumer acceptance and likelihood of adoption of smoked products. Consumer acceptability testing will include classic subjective measures of liking and relief of craving and withdrawal, but these measures are likely to lack sensitivity. The focus of this proposal is on objective measures of neurocognitive function. We will measure changes in event-related brain potentials (ERP) before and after smoking test cigarettes. There are a myriad of products, brands and sub-brands of smoked products. Here, for the purpose of illustration, we will discuss testing of menthol and non-menthol cigarettes and high and low pH products, manipulated by our Product Core B to differ only in the characteristics of interest. We present our aims specific to menthol and pH levels, acknowledging that the aims will expand with product characterization decisions, but that they illustrate the methods and design issues to be considered. To this end, are the following specific aims: Aim 1. To characterize and contrast consumer acceptability and likelihood of adoption of combustible tobacco products by comparing neurocognitive function, as indexed by event-related brain potentials (ERPs) in response to smoking test cigarettes with and without characteristics of interest. Aim 2. To determine the contribution of "throat grab" to tobacco product acceptability and likelihood of adoption. These aims will be accomplished through a series of within-subjects crossover trials; each trial will include the test tobacco product and comparison product, in four laboratory smoking sessions on different days and at approximately the same time of day ( $\pm 1$  hour). These illustrative studies will include: comparison of high and low pH products with and without throat anesthetization, and menthol and non-menthol cigarettes with and without throat anesthetization in separate laboratory visits among two cohorts.