University of Vermont Tobacco Center of Regulatory Science
Institution: University of Vermont
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Project 1: Low Nicotine Content Cigarettes in Vulnerable Populations: Economically Disadvantaged Women (Non-Pregnant)
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Project 1 Abstract:
Despite marked reductions in cigarette smoking in the general population, smoking rates among economically disadvantaged women have increased. Smoking among women of reproductive age is a particular concern because in addition to the usual health risks, there are additional risks should they become pregnant. A national nicotine reduction policy for cigarettes has considerable potential to reduce tobacco use, dependence, and improve health in these smokers. Controlled trials in general population samples have demonstrated that switching smokers to very low nicotine content cigarettes (VLNCCs) reduces cigarettes per day (CPD), dependence severity, and tobacco toxicant exposure. Our research during the current funding period indicates that disadvantaged women respond to VLNCCs with reductions in smoking rates, cigarette demand, dependence severity, and other measures of addiction. However, tobacco market conditions are likely to exert a considerable moderating influence over the effectiveness of a nicotine reduction policy. During the next funding period, we will utilize principles and methods of behavioral economics and behavioral pharmacology to model effects of a reduced nicotine policy among disadvantaged women when implemented alone or while providing a readily available substitute, non-combusted source of nicotine (e-cigarettes). To model the potential influence of flavors, e-cigarettes will be examined in tobacco flavors only or appealing personalized flavors. This study will be a multi-site trial using a between-subject, four parallel groups, pragmatic design. Disadvantaged female smokers (18-44 yrs) will be randomized to 16 weeks of: (1) normal nicotine content cigarettes (NNCCs) alone, the control condition; (2) VLNCCs alone; (3) VLNCCs + nicotinized, tobacco-flavored e-cigarettes (TF e-cigs); or (4) VLNCCs + nicotinized, preferred-flavor e-cigarettes (PF ecigs). Outcome measures include CPD, product demand, craving, appeal, toxicant exposure, brain function, and airway inflammation. In Week 17, participants will undergo an abstinence assessment to test whether the experimental conditions affect the ability to abstain from cigarettes. The integrative theme of this TCORS is **vulnerable populations**. The proposed research is highly relevant to CTP's scientific domains of **Addiction** and **Behavior** because it will test whether reducing the nicotine content of cigarettes reduces cigarette use, dependence, and product appeal, and whether these effects are enhanced by the availability of an appealing alternative source of non-combusted nicotine. It addresses the **Health Effects** domain by assessing effects on important biomarkers. It is **significant** and **innovative** because it will model how availability and appeal of ecigarettes may moderate the effectiveness of a national reduced-nicotine policy in an understudied, vulnerable population. Finally, it is **programmatic** as it will build upon work accomplished during the current funding period. Overall, this proposal has the potential to continue a productive, multidisciplinary program of research that will provide FDA with critically important evidence relevant to its regulatory responsibilities.