University of Vermont Tobacco Center of Regulatory Science
Institution: University of Vermont
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Project 3: Low Nicotine Content Cigarettes in Vulnerable Populations: Affective Disorders
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Project 3 Abstract:
Affective disorders (ADs; mood and anxiety disorders) are the most common mental health conditions in the US. Over 40% of people with ADs are current smokers, and they experience disproportionately high rates of tobacco-related disease and death. A national nicotine reduction policy for cigarettes has the potential to reduce tobacco 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) results in reductions in cigarettes per day (CPD), cigarette dependence, and tobacco toxicant exposure, with few adverse consequences. Furthermore, our work during the current funding period indicates that smokers with ADs respond to VLNCCs with reductions in cigarette demand and other measures of addiction. However, tobacco market conditions are likely to exert considerable influence over the effectiveness of a cigarette nicotine reduction policy. During the next funding period, we will utilize principles and methods of behavioral economics and behavioral pharmacology to examine the effects of VLNCCs in smokers with ADs, either alone or while providing a substitute non-combusted source of nicotine (e-cigarettes). In separate conditions, e-cigarettes will be provided in tobacco flavors only or in appealing personalized flavors. This multi-site trial uses a four parallel group, pragmatic design. Daily smokers with ADs 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 (TF e-cigs), or (4) VLNCCs + nicotinized, preferred-flavored e-cigs (PF e-cigs). Outcome measures include CPD, product demand, craving, appeal, psychiatric symptoms, biomarkers of brain function, and biomarkers of tobacco toxicant exposure and airway inflammation. After 16 weeks of use, participants will undergo an abstinence assessment in which we examine the effects of the study conditions on participants' ability to abstain from cigarettes and their responses to abstinence. 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 examine whether reducing the nicotine content of cigarettes reduces cigarette use, dependence, and product appeal, and whether these effects are enhanced by the availability of e-cigarettes. It will address the **Health Effects** domain by assessing the effects of these conditions on biomarkers of brain function, tobacco toxicant exposure, and airway inflammation. The proposed study is **significant** and **innovative** because it will model how availability and appeal of e-cigs may moderate the effectiveness of a national reduced-nicotine policy for cigarettes in an understudied population. Finally, it is **programmatic,** as it will build upon the work that we accomplished during the current funding period. Overall, this proposal has the potential to continue a highly productive multidisciplinary research program and will provide FDA with critically important empirical evidence relevant to its regulatory responsibilities.