University of Vermont Tobacco Center of Regulatory Science
Institution: University of Vermont
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Project 2: Low Nicotine Content Cigarettes in Vulnerable Populations: Opioid Abusers
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Project 2 Abstract:
Prevalence of smoking among individuals with opioid use disorder (OUD) is six-fold that of the general US adult population. Smoking is also associated with significant morbidity and mortality in this population, with the mortality rate of opioid-dependent smokers four times that of opioid-dependent nonsmokers and quit rates of approximately one-fourth that of non-substance abusers. A national policy of reducing the nicotine content of cigarettes has the potential to be an effective method of reducing the prevalence of smoking and smoking related adverse health outcomes in this vulnerable population. Controlled trials in the general population of smokers have demonstrated that switching smokers to very low nicotine content (VLNC) cigarettes results in reductions in cigarettes per day, cigarette dependence, and tobacco toxicant exposure, with few adverse consequences. Furthermore, our work during the current funding period indicates that smokers with OUD respond to reductions in the nicotine content of cigarettes with reductions in cigarette demand and other measures of addiction potential, although to a lesser extent that the other vulnerable smoker populations we have been examining. Considering the serious smoking-related disparities and adverse health consequences in the population of opioid-dependent smokers, we believe that an approach that combines e-cigarettes and also preferred flavoring represents a set of conditions most likely to produce a maximal effect on combustible smoking. Thus during the next funding period, we will utilize principles and methods of behavioral economics and behavioral pharmacology as we extend our research by examining the effects of reducing the nicotine content of cigarettes on cigarette smoking in this vulnerable population with and without substitute noncombusted nicotine products (i.e., e-cigarettes) readily available. We will also examine whether appeal of the non-combusted alternative is enhanced by flavors. In a multi-site, randomized clinical trial, we will use a between-subject, four parallel group, research design to evaluate the effects of VLNC cigarettes on smoking rate, dependence severity, and tobacco toxin exposure in smokers with current OUD. Participants will be randomly assigned to 16 weeks of exposure to (1) normal nicotine content cigarettes alone, which will serve as the control condition, (2) VLNC cigarettes alone, (3) VLNCs + tobacco-flavored nicotinized e-cigarettes, or (4) VLNCs + nicotinized e-cigarette with preferred flavoring. This design will be of direct utility to the FDA CTP by modeling possible market scenarios in which a reduced nicotine content policy may be implemented. Overall, this proposal has the potential to continue a productive multidisciplinary research program that focuses on the most vulnerable and least studied populations of tobacco users. This project will provide FDA CTP with critically important empirical evidence relevant to its regulatory responsibilities, while also contributing new scientific knowledge on reducing the addiction potential of tobacco products in vulnerable populations.