University of Vermont Tobacco Center of Regulatory Science
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Overall Center Abstract:
The overarching goal of this application is to renew the University of Vermont Tobacco Center of Regulatory Science (UVM TCORS). This multidisciplinary center is located at UVM but leverages close collaborations with Brown University, Johns Hopkins University, University of Pittsburgh, and University of Minnesota. The UVM TCORS focuses on a crosscutting **integrative theme** (vulnerable populations) and **two** of the scientific **domains** (addiction, behavior) of the Food and Drug Administration Center for Tobacco Products (FDA CTP). Building programmatically on research in the current funding period, we propose to focus our primary studies on three vulnerable populations, socioeconomically disadvantaged women of reproductive age/pregnant individuals with comorbid opioid use disorders, and individuals with comorbid affective disorders. Each of these populations is at increased risk for tobacco use, dependence, and tobacco-related adverse health outcomes. Despite their increased risk, these populations are often excluded from tobacco regulatory studies, leaving a significant knowledge gap. The overall goal of the UVM TCORS is to provide FDA CTP with sound scientific evidence on the impacts of tobacco products in vulnerable populations, a topic that is critically important to FDA CTP effectively executing its tobacco regulatory responsibilities. Regarding specific regulatory priorities, we will continue to focus on reduced nicotine standards in combusted tobacco products. We have designed our studies in vulnerable populations to align with those conducted in healthier populations by the University of Pittsburgh/University of Minnesota TCORS. The primary trials proposed in this application will examine the extent to which the availability and appeal of alternative non-combusted sources of nicotine (i.e., e-cigarettes) may moderate the impact of reduced nicotine standards on reducing cigarette smoking. That topic will be investigated in each of the primary vulnerable populations of interest using common protocols to the extent possible, and also protocols that facilitate comparisons with studies in healthier populations as noted above. We propose to continue our Administrative and Career Enhancement Cores. The Administrative Core supported completion of three multisite studies, with three others underway, during the past 4 years, along with numerous pilot/developmental studies. Cumulatively, those projects resulted in 58 publications in peer reviewed journals and many more presentations at national scientific meetings. We are proposing a plan to effectively recruit and implement pilot and rapid-response studies. We propose to continue a highly effective predoctoral and postdoctoral mentoring program comprising 10 fellow slots that have been continuously filled during the current funding period. We will continue contributing to FDA CTP conferences and other scholarly initiatives, and plan to continue leading the Vulnerable Populations TCORS Workgroup and to participate in others. Overall, UVM TCORS is well positioned to be a valuable asset to FDA CTP and others with interests in tobacco regulatory science especially as it applies to vulnerable populations.