Integrated Health, Behavioral and Economic Research on Current and Emerging Tobacco Products
Institution: University of California, San Francisco
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PROJECT 2: SHORT-TERM CARDIOVSCULAR EFFECTS OF E-CIGARETTES: INFLUENCE OF DEVICE POWER AND E-LIQUID pH AND HOW E-CIGARETTES COMPARE WITH HEAT-NOT-BURN PRODUCTS
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Project 2 Abstract:
Components and parts of electronic cigarettes (e-cigarettes), such as batteries and e-liquids, are within the Food and Drug Administration's regulatory authority. There are, however, significant gaps in understanding of how specific aspects of these components and parts influence the overall health effects of e-cigarettes, including short-term cardiovascular effects. E-cigarette power is an important determinant of aerosol generation, nicotine delivery, and the type and amount of toxicants generated in e-cigarette aerosols, but the influence of power on these cardiovascular effects has not been described. In addition, the influence of e-cigarette liquid (e-liquid) pH on rate of systemic nicotine absorption, nicotine-induced sympathetic nervous system stimulation, and heart rate increase, a risk factor for cardiovascular disease, is not understood. There is a similar lack of knowledge about the health effects of heat-not-burn (HNB) products, which heat tobacco without combustion. It is expected that HNB products will compete with conventional cigarettes and e-cigarettes. Philip Morris Products S.A. has filed an application with the FDA to market its HNB product, iQOS, as a modified risk tobacco product in the U.S. Differences in the cardiovascular disease risks between e-cigarettes and HNB products are unknown. This project has three ***specific aims*** to fill these gaps: (1) Determine the impact of e-cigarette power on nicotine pharmacology, systemic exposure to toxic volatile organic compounds (VOCs), and short-term cardiovascular effects; (2) Determine the impact of changes in e-liquid pH on nicotine pharmacokinetics, cardiovascular, and subjective effects of e-cigarettes; and (3) Compare differences in nicotine pharmacology, systemic exposure to toxic VOCs, and short-term cardiovascular effects of e-cigarettes to heat-not-burn tobacco products. These aims will be achieved through three within-subject crossover human pharmacology studies, one study for each aim, which will be conducted on a hospital research ward with healthy users of e-cigarettes and/or iQOS. Power and e-liquid pH will be manipulated in aims 1 and 2, respectively, and the endpoints will be markers of cardiovascular disease risk. The third aim will be a within-subject comparison of toxicant exposure and the cardiovascular effects of e-cigarettes compared to iQOS. This study of ***health effects*** will contribute to knowledge of the influence of e-cigarette characteristics on their short-term cardiovascular effects, and the cardiovascular effects of e-cigarettes compared to iQOS as part of the UCSF TCORS integrated theme that "understanding combined ***health effects, behavior,*** and ***impact analysis*** will provide actionable information for regulation of and public communications about current and emerging tobacco products." These studies will provide the FDA with detailed and specific information on short-term cardiovascular effects of e-cigarettes to inform regulation of e-cigarette power levels and a specific e-liquid characteristic (pH), as well as inform FDA regulation of emerging HNB products.