The University of Vermont (UVM) is one of 14 institutions nationwide to obtain a prestigious Tobacco Centers of Regulatory Science (TCORS) award from the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH). FDA and NIH formed an interagency partnership to fund this new, first-of-its-kind regulatory science tobacco program. UVM’s TCORS grant totals $19.5 million.

Stephen T. Higgins, Ph.D., UVM professor of psychiatry, director of the new Vermont Center on Behavior and Health at UVM, and a nationally recognized expert in addiction, contingency management and behavioral economics, will direct the Center. John Hughes, M.D., UVM professor of psychiatry and an international expert in smoking cessation, will serve as the Center’s associate director. In addition, internationally recognized collaborators and consultants from Brown University, Johns Hopkins University (Maxine L. Stitzer, Ph.D.), University of Minnesota (Dorothy Hatsukami, Ph.D.), and University of Pittsburgh (Eric Donny, Ph.D.) will support the UVM Center’s research.

The TCORS will reside within UVM’s new Vermont Center on Behavior and Health, which serves as a foundation for the UVM Neuroscience, Behavior and Health Initiative.

The TCORS grant marks the first P50 award to be received at the University of Vermont. According to the NIH, P50 grants – which are categorized as “specialized center” grants – are usually developed in response to an announcement of the programmatic needs of an Institute or Division and centers receiving this funding may serve as regional or national resources for special research purposes.

The Family Smoking Prevention and Tobacco Control Act, passed in June 2009, provided the FDA with the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health. On April 22, 2013, in compliance with Section 918 of the Food, Drug & Cosmetic Act, a report was submitted to the U.S. Congress, which was compiled “after consultation with recognized scientific, medical, and public health experts, that ‘examines how best to regulate, promote, and encourage the development of innovative products and treatments (including nicotine-based and non-nicotine based products and treatments) to better achieve, in a manner that best protects and promotes the public health.” Following the presentation of this report, the FDA was granted legal authority to set standards on how much nicotine tobacco products contain. However, the law prohibits setting the standard at zero. The TCORS research will provide the FDA with scientific evidence on how existing and new tobacco products impact public health, providing a foundation on which it will base its tobacco regulatory decisions.

The UVM TCORS efforts will be particularly focused on nicotine content. Nicotine is the constituent in tobacco that drives repeated use and addiction, so long as there is a sufficient level present to activate the brain’s reward centers. The UVM TCORS will assist the FDA in determining whether there is a nicotine content level that is below the threshold for producing addiction, and importantly, that lowering nicotine levels does not produce unexpected negative health consequences. This work has tremendous potential to reduce smoking prevalence and improve the U.S. public health by keeping young people from ever getting addicted and increasing the chances that those who are already addicted can quit. –continued–
The UVM TCORS will conduct double-blind research studies in three areas articulated by the FDA. One—an effort that will take place at UVM and two other sites—focuses on an assessment of tobacco products in vulnerable populations, including economically disadvantaged women of childbearing age/pregnant women, individuals with other substance use disorders, and individuals with serious mental illness, all of whom are at increased risk for smoking and its adverse health effects. Another, which will involve an examination of the effects of nicotine content on individuals with psychiatric problems, such as depression, will be led by UVM’s partners at Brown University. The third trial will focus on the effects of nicotine in people with opiate dependence. These populations are typically excluded from tobacco regulatory studies. Providing that information will be the mission of the Vermont TCOR.

UVM TCORS Researchers

- UVM faculty members Diann Gaalema, Ph.D., assistant professor of psychiatry, Sarah Heil, Ph.D., associate professor of psychiatry, and Stacey Sigmon, Ph.D., associate professor of psychiatry—all addictions research experts—will lead the multi-site clinical trials at the core of the UVM TCORS.
- Ira Bernstein, M.D., professor and chair of obstetrics, gynecology and reproductive sciences, and Kelley McLean, M.D., assistant professor of obstetrics, gynecology and reproductive sciences, will assist in examining how tobacco products impact women’s reproductive health. This will be a special focus unique to the UVM Center.
- Hugh Garavan, Ph.D., associate professor of psychiatry, and Alexandra Potter, Ph.D., assistant professor of psychiatry, will lead the clinical neuroscience and neuroimaging research, examining the impact of tobacco products on neuropsychology and brain functions related to addiction vulnerability and recovery.
- Russell Tracy, Ph.D., professor of pathology, Philip Ades, M.D., professor of medicine, and Kathleen Brummel-Ziedins, Ph.D., associate professor of biochemistry, will assist in examining the impact of a variety of tobacco products and nicotine levels on cardiovascular health.
- Charles Irvin, Ph.D., professor of medicine and director, Vermont Lung Center, and Anne Dixon, M.D., professor of medicine and director of pulmonary and critical care medicine, will assist in examining the effects of these products on lung function.

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