

**Notification Alert: Research Involving E-Cigarettes/ENDS
 (October 2, 2019)**

It has come to our attention that a number of VA facilities are conducting interventional and observational studies involving e-cigarettes also called electronic nicotine delivery systems (ENDS). E-cigarettes/ENDS are devices that heat a liquid into an aerosol that the user inhales. The liquid usually has nicotine and other additives. E-cigarettes/ENDS are considered tobacco products by the FDA because most of them contain nicotine, which comes from tobacco. There are increasing concerns about the health risks associated with use of e-cigarettes/ENDS. The U.S. Surgeon General issued an Advisory on E-Cigarette Use among Youth, and on August 30, 2019, the Centers for Disease Control and Prevention (CDC) issued a health advisory titled, “Severe Pulmonary Disease Associated with Using E-Cigarette Products”. Research subject safety is always the first priority for any VA research study. The CDC health advisory is information that any prospective or currently enrolled subject should be made aware of as information that relates to potential risks of participating in the study as well as information that may relate to the subject’s willingness to continue participation in the study.

Given the recent CDC health advisory, the VHA Office of Research and Development (ORD) is advising VA Investigators and VA facilities to review any projects in your research portfolio involving e-cigarettes/ENDS and consider the following:

1. Have enrolled subjects been made aware of the CDC health advisory?
2. Have recruitment and/or informed consent materials been updated to reflect the information in the new CDC health advisory?
3. Has your IRB and VA Facility’s Research and Development Committee considered whether it is in the best interest of the subjects and the institution to continue if a study is ongoing involving e-cigarettes?
4. Did the IRB consider the e-cigarettes as tobacco products (i.e., Are the products and materials marked with appropriate FDA approved warnings)?
5. If the VA research is a smoking cessation study (including a change from combustible to non-combustible nicotine products), did the IRB apply the applicable FDA regulations (21 CFR 50/56 312 and/or 812) to the study for an investigational use since e-cigarettes/ENDS are not an FDA approved smoking cessation therapy?

ORD is not at this time placing a prohibition on the conduct of VA research involving the use of e-cigarettes/ENDS. However, it is important that IRBs and VA Research and Development Committees are aware of the CDC health advisory regarding e-cigarettes/ENDS in the evaluation of research involving e-cigarettes/ENDS and also ensure that VA subjects are given information needed to make informed decisions about participating in research involving e-cigarettes/ENDS.